IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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IDENIX PHARMACEUTICALS, LLC, and UNIVERSITA DEGLI STUDI DI CAGLIARI,	:	CIVIL ACTION
Plaintiff,	:	
v	:	
GILEAD SCIENCES, INC.	:	
Defendant.	:	NO. 14-846-LPS

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Wilmington, Delaware
Thursday, September 7, 2017
Oral Argument Hearing

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BEFORE: HONORABLE LEONARD A. STARK, Chief Judge

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P R O C E E D I N G S

(REPORTER'S NOTE: The following oral argument hearing was held in open court, beginning at 11:09 a.m.)

THE COURT: Good morning, everyone.

(The attorneys respond, "Good morning, Your Honor.")

THE COURT: I'll have you put your appearances on the record for us, please.

MS. PARKER: Good morning, Your Honor. Stephanie Parker.

THE COURT: Good morning.

MR. DAY: Good morning, Your Honor.

THE COURT: Good morning.

MR. DAY: John Day from Ashby & Geddes for plaintiff Idenix. Stephanie Parker, Calvin Griffith, Ryan McCrum, and Michael Weinstein, all from Jones Day at counsel table. Jennifer Swize, Brian Lea, that is spelled L-e-a, in the second row. And then in the gallery, John Kinton, Anthony Insogna, Bradley Harrison. And behind them, Greg Castanias also from Jones Day.

THE COURT: Okay. Thank you. Welcome again to all of you.

Good morning.

MR. McCANN: Doug McCann from Fish & Richardson

on behalf of Gilead. With me are John Singer, Chad Shear, Frank Scherkenbach, Joseph Warden, Martina Hufnal, all of Fish & Richardson. Jason Sheasby of Irell & Manella on behalf of Gilead. And from our client, Brett Pletcher, Lorie Ann Morgan, and Andrea Hutchison.

THE COURT: Okay. Welcome to all of you as well. So we're here for argument on multiple motions, let's call them. Have you all conferred how you might like to present them today?

MR. SCHERKENBACH: We did, Your Honor.

THE COURT: Okay.

MR. SCHERKENBACH: And unless the Court has a different order in mind, the parties agreed that we would start with Gilead's motion on the 112 issues, both written description and enablement.

Followed by Gilead's motion on damages.

Followed by Idenix's motions on enhancement/fees.

THE COURT: And that is agreeable to the plaintiff; correct?

MR. GRIFFITH: It is, Your Honor.

THE COURT: That's fine.

MR. SCHERKENBACH: Thank you. Mr. Singer will address the 112 issues for Gilead.

THE COURT: Okay. Then we will begin with that.

MR. SINGER: Permission to approach, Your Honor. I have some handouts.

THE COURT: Certainly.

(Slides passed forward.)

MR. SINGER: Your Honor, before I begin and kind of address the parties' arguments in the papers, I just wanted to say that it's often the case on JMOL we're here on, maybe I shouldn't call it that but I will, somewhat mundane affairs where simply sometimes we want to preserve the appellate record. I think today we are not.

I think before you today on these 112 issues you have a very important issue for the development of the life saving medicines in this country, and that really in a nutshell is whatever the contribution a patentee makes to the field or science at issue, whatever the contribution the patentee made in this case, when claims are so broad that they fail to or they really contract from innovation by charging sort of rent for which they fail actually to teach. And I think in this case the '597 patent falls on the wrong side of that line. It doesn't disclose or teach the entire class of 2'-methyl up nucleosides to treat HCV.

Instead, at best, what it does is it encourages accepting what the characteristics of the invention described. It encourages others in the field to go find those 2' methyl up compounds that actually treat HCV with

their own experimentation and their own effort. And that, in our view, renders the patent invalid both under enablement and written description.

THE COURT: Where we are with the record, and I'm sure we'll talk about that a lot but we are on JMOL.

MR. SINGER: Yes.

THE COURT: I think that probably means that there is evidence that the 2'-methyl up discovery was important, perhaps key, perhaps crucial.

If we accept that there is evidence to support that, is there some claim that Gilead would allow, could have been legitimately claimed as an invention?

MR. SINGER: Sure. Surely, of course.

THE COURT: Give me an idea of what a claim like that would look like that would be physically enabled and have written description.

MR. SINGER: Based on the disclosure that is in the claims, the claim to the 2'-methyl up class with hydroxy down would have been absolutely supported by the patent specification and enabled by the patent specification.

And that is the data that was in there, the exemplary compounds that were in there. And that was, in fact, the discovery described by Dr. Sommadossi. I think that is fair to say would be perfectly fine. It would have, if you will, cabined or confined the invention to that,

number one, that which was actually invented and, number two, not run afoul of the case law that I think both parties are thinking about in the enablement and description context.

THE COURT: Would not have been too abstract, for instance, to be patented in your view?

MR. SINGER: No. I mean, Your Honor, it has, it has exemplary compounds, 2'-methyl up, OH down. Those are the compounds that are actually described in the specification as examples, and it wouldn't have been abstract in any way in the sense of having actually made those compounds and exemplified them in the patent specification to treat, to treat the disease at issue.

It's when going beyond that, to then say that the discovery of that, if you will, group, however large or small it might be, to then go from there, that teaching to then say I have and claim any 2'-methyl up compound regardless of its substituent at the 2' down or, frankly, at the other positions in the molecule as well that the patent runs afoul of the enablement and written description laws.

THE COURT: And what we have in the '597 specification in Gilead's view is adequate to support both written description and enablement, that more limited claim that you just described?

MR. SINGER: Right. I think we said that in our

papers, Your Honor.

Your Honor is familiar with the patent policy behind them. I'm going to start with enablement, Your Honor. Most of my discussion beyond that now will go to written description but they do have a lot of overlap.

You're familiar with the patent policy. You asked us to look at the Enzo case and provide you with briefing, and we did.

These are the policies here that are at issue, and it really is as I described, when does the patentee go too far -- having discovered something and then go too far to claim that which they don't teach or disclose?

I wanted to point out really what I think is what you and I just discussed, and this goes to the exemplary compounds that are in the patent specification. And what we have described in our briefing.

And if you look at -- this is I don't think controverted at trial at all. The sugar, the nucleoside is the sugar on the left side in the bottom. This is slide 3. And in the right corner, of course, is the base. And you see that, of course, the sugar in the working examples and as described by Dr. Sommadossi's discovery is identical.

So we have, and I think Idenix pointed to one or two examples, but they all have this same sugar. And it's got the methyl up at the 2', and the OH down at the 2', the

OH down at the 3', and the base is different.

You have got the four different natural bases in this depiction but the sugar is identical, and that's where the rubber hits the road. Because when it came time for claim construction, Idenix urged, and the Court adopted, this claim construction that then unbounded the sugar, really that is what happened. We have any purine or pyrimidine base, so anything on the right, and then this 2'-methyl ribofuranosyl nucleoside became any five member sugar ring, as the Court knows.

So this is the Court's construction. So that extension to this broader, sort of this broader sugar structure or any sugar, almost any sugar with the 2'-methyl up, that is where it is brought in.

So I want to pause on this, Your Honor, because I think it's common to the cases the party talk about, including the *Enzo* case and the *Wyeth* case. And it is we think an important aspect of these claims, and it is how we presented the argument at trial.

So the claim scope, it kind of has this structure, the claim itself has a structure where it identifies a structure and the structure is really any nucleoside with the attributes listed on the slide, 2'-methyl up, and according to the Court's claim construction, any non-hydrogen substituents at 2' down, 3'

down, and any substituents at 3' up, 4' and 5', and any purine and pyrimidine base.

This is not to say -- they say a person of skill wouldn't do anything. And we agree with that, but the claim construction covers anything that anybody comes up with that meets that definition.

And then it is circumscribed. So this group, this broad group of structures is then circumscribed by the function of being effective.

The critical aspect that Idenix has focused on, the expert has focused on and said, here is the key. This is Dr. Meier who was testifying at trial.

These were the key teachings according to him. The key invention or the key structures are 2' methyl up, and it should be an inhibitor of the NS5B polymerase. That's the enzyme involved here in the replication of the virus in order to try to block that replication.

Well, you know, that inhibition of the NS5B polymerase, that's not a claimed feature. I don't think the Court really has to resolve that to resolve these motions in Gilead's favor. But that is what is said is the key, what a person, a skilled person would take from that structure I just described to you as to how the claim works.

And so if you go to the patent, and I think this is quite clear, the patent tells the person of skill in the

art, you know, in order to find those compounds that have the key structure of the 2' methyl up and that would inhibit the polymerase and therefore be effective to make and screen the compounds. That's what you do. You make them and then you screen them, and the experts for Idenix, they agree. That's what they said.

Here's Dr. DeFrancesco talking about this very paragraph. Just for record, Your Honor, this is column 13, lines 42 to 49 of the '597 patent. This quote is actually in there twice, so if you see it at a different site, it's in there twice as well. It says the Beta-D and Beta-L nucleosides of this invention may inhibit HCV polymerase. That's that enzyme. And nucleosides can be screened for their ability to inhibit HCV polymerase activity in vitro according to the screening methods. And as I said, that's what the experts said, Idenix's experts. This is not -- we're looking at, you know, we have to, of course, for JMOL, look at the evidence most favorably to Idenix. We have to draw the reasonable inferences one my draw that the jury can draw, and here's Dr. DeFrancesco. If you remember, Your Honor, he was the virologist that testified for Idenix. And he said, we used the screens because that is the way you actually cut down the number of compounds, by removing all inactive ones to a few interesting ones.

And this is Dr. Meier, both actually referring

to this very paragraph. This was highlighted by Idenix in their examination and this is them talking about this very paragraph in the patent. Dr. Meier, this is from column 13, the section that I copied here. Nucleosides can be screened for their ability to inhibit HCV polymerase activity, et cetera. Make them and screen them. That's how you find the ones that are active or effective against --

THE COURT: You're saying make and screen. It seems like these quotes are talking about screening. What is the record evidence on whether a person of skill in the art at the appropriate time would also have to take time to make the compounds?

MR. SINGER: I think that Dr. Meier talked about the, Dr. DeFrancesco didn't talk about making. Dr. Meier talked about having to make them. And the question he was talking about, the methodologies in the patent, talking about the manufacturing methods that were in the patent at this very location in the transcript. I can get you a cite in a moment where he talks about, you have to make them to screen them. They weren't simply commercially available. You have to make them and screen them. That's the point.

THE COURT: And does that contribute to whether or not, to an assessment of how much experimentation is required?

MR. SINGER: I think it does. Just the simple

fact that one has to make them certainly does and the fact that one has to screen them. And it isn't the issue, Your Honor, I think Idenix has argued, you know, that the nucleoside chemistry itself was a known field. People had been making nucleosides for quite a long time, and Dr. Secrist surely acceded to that in his cross-examination. But one still has to go about making these, you still have to do that. You have to do that process to make them.

And in our briefing, Your Honor, the time required, it was uncontested at trial, that Dr. Secrist said the person of skill could make two to four a month, a single person of skill. And if you remember, if the Court doesn't want to rely on Dr. Secrist on the assumption that the jury rejected anything he said, I don't think it would be a fair and reasonable inference. Idenix's witness said that she thought screening, which, of course, requires making 37 compounds a lot, in a month was a lot. That I think was Dr. Tausek was her name. We cited that in our papers as well.

So there is this rate limiting feature in the patent of making and then screening. And while Dr. DeFrancesco did testify that one could in theory screen thousands per month in the abstract, what the testimony was, you have to make them and acquire them. And as I said, Dr. Tausek said 37 a month was a lot. Dr. Secrist said the average person of skill could make two to four of these

nucleosides per month.

And, you know, at times reading, you know, Idenix's papers, I don't mean to make light of this, but it almost sounds like granting JMOL is impossible because enablement is a factual issue and all the facts were resolved again Gilead, and so therefore it's kind of a circular argument. There are facts involved. The jury solved them against you, and therefore you lose, and therefore JMOL is impossible. But, you know, we've cited, and surely the Court has plenty of experience with JMOL, that you don't just ignore the evidence that doesn't support the verdict, particularly where it's uncontradicted and unimpeached, as I believe the testimony I just described from both Dr. Secrist and Dr. Tausek was.

THE COURT: Enablement, I think is a question of law at the end of the day. Correct?

MR. SINGER: That's right. That's correct.

THE COURT: Correct me if I'm wrong. Did you ever move for summary judgment on enablement?

MR. SINGER: We did not move for summary judgment on enablement.

THE COURT: I've never been asked to determine whether there's even a genuine dispute of material fact.

MR. SINGER: That's correct, Your Honor. We moved on written description, I believe, twice, if memory

serves me. But I think it's important, Your Honor, to look at, here are sort of the key kind of, some of the key points that there's just no dispute about one way or the other at trial, and these are the background facts that are critical to the enablement analysis. This is Dr. Meier. Modified nucleoside activity for HCV in its infancy. That's their own expert. Dr. Gosselin. If you recall, he appeared on video, Your Honor, on the Idenix side. You don't know whether or not a nucleotide will have activity against HCV until you make it and test it, and there's that making and testing again.

And we pointed it out in the papers, Your Honor, but it's important to pause on it. This is a document that was entered into evidence with Dr. Seeger and it records Idenix's activities with the 2' methyl up OH construct. Not anything else done, but just the 2' methyl up OH construct. Even that I already said would have been enabled, even that more often than not results in inactive compounds. When you make those, and Dr. Seeger is talking about this log that Idenix made of hundreds of compounds, and this.

These are examples of compounds that were not active. All of them in this Idenix log; right? Correct. Just what do they have in common? They have in common that they are 2' methyl up OH down compounds. That's not to say every compound in this log was inactive. That's not right.

It's just that a lot of them weren't, so we have a very unpredictable field in which people take the time to make compounds and they can't predict the activity. They have to test them. And then that's how they find it. That doesn't satisfy the laws of enablement.

And you had a vivid example, uncontested, with -- now we're going to move away from the OH down, which was the thrust of the disclosure. This is Dr. Otto talking about, okay. Let's talk about fluorine down. What happens when you have fluorine down to the 2'? And Mr. McCann asked Dr. Otto about 6130. And if Your Honor will remember, that was the key compound that Pharmasset first invented in 2003. And I've got the little picture at the bottom there, Your Honor, right there. And you see the fluoro down at 2' with the methyl up. And it says, 61 is sugar ring. Can you describe to the jury, again, what is at the 2' position? The 2' position has 2' methyl up and fluorine down. Talks about the base being cytosine and says that it's active. And then Dr. Otto talked about switching the base, even the base. Just switching the base from cytosine to adenosine, one of the naturally occurring bases in all of our bodies. Did Pharmasset ever try keeping that exact same sugar ring and switching the base to the adenosine base? Yes. And what happened? The compound was inactive. So what difference does that make there? And, again, it is not to

say one compound carries the day. The evidence at trial was uniform, that predicting the activity of these compounds is not possible until you make them and test them.

We think under *Wyeth*, under all the case law we've cited, this is basically an iterative and trial-and-error process to practice the claimed invention even with the help of the specification that renders it invalid.

THE COURT: Is it Gilead's position that the full scope of the claims as the Court has construed it could not possibly be enabled or is there some conceptual enablement test that could have, some other specification that could have enabled it?

MR. SINGER: Sure, Your Honor. I can imagine a world -- we're lawyers, so we can always imagine other hypothetical specifications that had, you know, many more examples with many more different, for example, substituents at 2' down and 3' down that showed the world, hey, 2' up methyl compounds with all of these other things down have activity or not have activity.

THE COURT: Even some of them would have presumably said, no activity. You know, we tested this. This one had no activity, but some of these other 2' downs did have activity?

MR. SINGER: Sure. I think the case law, I

think it was the *UroPep* case kind of talked about the mere listing of inoperative embodiments, you're kind of -- it's sort of an unfair thing, right. You have to list everything, and if you listed a few that were inoperative, would that render your claim not enabled? And the answer is no. But I surely -- surely, we can imagine a specification that had more than one sugar ring to disclose to the world attached to the four natural bases and a couple modified bases. We can imagine other substituents down. Of course, we can, could have imagined fluoro down, which, of course, this patent omits from its description of possible, of substituents. So, you know, that's not the case we have here, Your Honor, but absolutely. We can imagine something that would be the standard.

And, you know, we've cited a variety of cases, and I'm struck, Your Honor, I think we're all struck by how similar the *Wyeth* case is, and I put the claim side by side with *Wyeth* just so we could see. It has this exact same claim structure. You've got the method for treating. You've got a structure. In the case of the *Wyeth* case, it was the Rapamycin structure which has having this macrocyclic ring. I will describe it in a moment with a substitution at the C37 position. And here we have the 2' methyl nucleoside, the 2' methyl position and substitutions at the other points.

Again, the constructions define the classes in the same way. There's the *Wyeth*. The invention is a new method of use of a known compound, sirolimus and any other compounds that meet the constructions structural and functionality requirements. You've got the new use of what Dr. Sommadossi described as the known compound and then extended to anything that was unknown that had that structure as well, and then circumscribed by the effectiveness in the claims.

And, again, *Wyeth*, very limited knowledge of the use of these compounds for the particular disease, the restenosis in the arteries. And remember in that case, Your Honor, Rapamycin was known since the seventies. That was not an unknown compound. In fact, Idenix cited, provided the Court with a rapamycin patent at issue in the case, and if you read the patent, you'll see it's a well-known compound that has been used for a variety of things for many decades before the *Wyeth* case.

The same thing here. While some of these compounds, these nucleosides were known, and as Dr. Meier described, that people had been doing nucleoside chemistry for a long time. The field of actual use here was basically unknown in its infancy.

Unpredictability, the same thing. You've got to test it, you've got to make it and test it to find the

activity.

And this I've already described, the use of a known compound extended to a class. And, again, the structure at issue impacted potentially very large numbers of compounds described by the effectiveness limitation. And whether it's billions or simply a lot or millions, at the end of the day, what you have is an iterative trial-and-error process to find the compounds by making and then testing it.

All right. And it's ironic to even use the exact same language. The expert said it's significantly smaller than *Wyeth* because of the particular molecular weights that we required to make it permeable, and Dr. Meier said the same thing. It would be significantly smaller because it would have to inhibit the NS5B polymerase. That doesn't matter because at the end of the day, it's the person of skill who has to find them.

And this I want to pause at. The data available in the patents is remarkably similar. And in *Wyeth*, they had in vitro test data about one particular compound. And then if the Court recalls, they assume that there are four other compounds that shared structural similarities that had that same activities. Five, five in total.

And here it is the same thing. We have four compounds that are said to be active that share a common

structural feature of the 2'-methyl up and are said to have activity, so the exact same number of compounds. And it is time consuming to do this.

And this is Dr. Taucek's testimony I referenced where she said the 37 compounds a month was a lot.

So that is the *Wyeth* case. And I think it well establishes facts looked at in light of, in favor of Idenix.

I want to respond a little to Idenix's arguments. And I'm sure I'll hear more, but just what they said in the papers. I don't know what is going to be said here today.

Idenix responds to this and says, well, there is guidance in the patent specification that it is, it does tell you what to do at these other positions. And this is from their brief.

They say, Dr. Secrist -- excuse me. The evidence showed using the '597 patent disclosure combined with the knowledge in the art would allow skilled artisans to readily visualize the other compounds expected to have antiviral activity.

They talk about -- this is page -- I don't have the page number. I apologize, Your Honor. Dr. Meier talks about that key testimony that I highlighted. The key structure being the 2'-methyl up and NS5B activity.

And the brief goes on and says, such compounds

include 2'-methyl prime ribonucleosides having substituents at the 2' down position that would mimic hydroxy in some way, shape, or form. Factors such as steric hindrance and electronegativity of compounds would inform skilled artisans of modifications at the 2' position that are likely to work.

This is not Dr. Meier's testimony. If the Court will recall, on summary judgment of written description, Idenix said he would testify to this at trial. And he did not.

He did not offer any testimony about mimicry or steric hindrance. What they're pointing to is the videotape deposition testimony of Dr. Storer talking about what he did at Idenix after the patent filing. And that simply is not enough to overcome or -- that is not substantial evidence. That is not enough to overcome or support denying JMOL.

THE COURT: Because of the timing with which Dr. Storer did the work?

MR. SINGER: Because of the timing. It is after the patent. It is also not from the perspective of a person of ordinary skill in the art.

And, most importantly, you know, perhaps, it's not in the patent specification. If this is the novel aspects of one of the novel aspects of the invention, it has to be in there. And I apologize we don't have a cite there from *Enzo* I which is just a cite.

But it is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement.

If the novel aspect is the activity of methyl up with anything at these other positions, if the mimicry and steric hindrance is that novelty, the other aspect of the invention besides being known, OH down, that has got to be in the patent specification. And this testimony does not put it in.

And, critically, it is not from an expert offering that this is what a person of ordinary skill in the art would conclude. This is we're talking about what Idenix did internally after the patent.

So I don't need to go through this again. I provided to Your Honor just a simple chart of the similarities to *Wyeth*.

I did want to pause, Your Honor, assuming I don't take too much time, and also talk a little bit about *Enzo*. And, again, I look at that case, and it's got the same kind of structural component and then a functional component. And, again, the structure and the function put together left the person of skill having no choice to make a variety of things to see if they would properly hybridize and be able to be detected in an art with the knowledge with limited examples. A large class you had to winnow down to

find the things that work, that is not enablement.

And then also on *Liebel-Flarsheim*. That is the case Your Honor will remember we were talking about with respect to the impact of the failure of Idenix to be able to make the 2'-methyl fluoro construct themselves.

And this is again right back to the policy issue I started with. It's important to remember the claims as filed didn't allow for the 2'-methyl fluoro down, and they were amended to kind of bring that within the full scope of the claims.

As we have already heard, and the Court knows very well, the 2' prime fluoro is not listed in the patent specification, and Idenix failed to make the accused product when they tried and now essentially they want credit for Dr. Griffon unknowingly making it in 2003.

Okay. Let's say that he unknowingly made it in 2003 and the jury believed that. That doesn't change the fact that no one at Idenix actually identified a working synthesis until 2005, after multiple years of failure of either by their experts.

So this is right on *Liebel-Flarsheim* where the claims are expanded as they are here. Their full scope isn't enabled when the patentee itself fails to be able to make the accused product and the accused structures that fall under the claims.

This was right back to the teachings or the lack of teachings that I described here.

What other response do they have? They say, well, look, Jeremy Clark himself was guided by the '597 patent. We talk about going to Dr. Otto's office. Somehow that proves that the patent is enabled because Mr. Clark, he was able to use the '597 patent to do this work.

There are inferences, and there are reasonable inferences, Your Honor. And there is no doubt Mr. Clark did go into Mr. Or Dr. Otto's office with the patent. And the testimony at trial was they were trying to see whether or not they were infringing or not.

Here is what he said. This was presented to the jury about you can't rely on some portion of Mr. Clark's testimony and ignores others.

This is what he said about where he got the idea from:

He was asked: Where did you get the idea of using 2'-methyl up and 2'-methyl down?

He said: Probably from reading the literature.

You go back to the old literature. This was the Merck material that were at trial.

The 2'-methylcytidine compounds were made in the late 60s or reported at least in the late 60s.

Then they say, well, he did it in 15 minutes.

If the Court looks at the testimony that is cited there, Your Honor, he said the reaction took 15 minutes. So he actually, you know, put the chemicals together. It took 15 minutes for a chemical reaction, as I suppose chemical reactions I suppose sometimes do.

What he really said was, let me tell you about the synthesis with the sugar. This is page 976, line 22:

It was the spawn of the devil. This took me many, many times of going back and doing the same steps over and over.

Then when asked where he got a particular part of the reaction: Do you recall how you arrived at the methyllithium reaction, how you came to use the methyllithium, he didn't say he got it from Idenix. He said he got it from a work by Matsuda, a Japanese scientist.

That does not answer the enablement question.

THE COURT: You say that you can't take part of Mr. Clark and not all of it. Why wasn't the jury free to say we believe him on some things and we don't believe him on others?

MR. SINGER: They are, but I would just -- the law requires the inferences be reasonable. And what Mr. Clark said -- so the inference from the testimony, Your Honor, has to be reasonable, it can't just be I'm going to take one part of Mr. Clark's testimony and just ignore and

ask for the inference, because Mr. Clark did not directly say -- he didn't, he didn't go to, he didn't offer any testimony that I used Idenix's patent to guide me. This is an inference that Idenix argued to the jury.

So I put up what he actually said and what he actually did and I ask Your Honor, I don't believe that that is a reasonable inference to conclude that the '597 patent was the solution to its properties.

And, finally, Your Honor, just on the disclosure point. The patentee's failure, at the end of the day, not the infringer's success, is what really matters. And the disclosure in the '597 patent by Dr. Meier's own words was the known routine methods of making nucleoside. It wasn't anything -- he do not describe it as putting anything new in there. So persons of skill would turn to these methods and adapt them as they might need to to make these 2'-methyl up and whatever they were going to put down.

Okay. *UroPep* came up, Your Honor. I would submit that is a very different case. I believe Idenix is citing it for the proposition both relevant to enablement and written description. Either way, the field was described by the Court as a mature field in the case. And there were hundreds of these known inhibitors of selected inhibitors of the particular enzyme in the case at the time of the invention. So it was a new use of these hundreds

of known inhibitors, and literally, I think the Court said thousands, tens of thousands have been developed since the time of the invention. So this was a very mature field right there.

Dr. Bell testified the field was mature. And that a skilled artisan would not necessarily need to conduct any screening but could use their own PDE5 inhibitor, if they've got one already. And that is because the field was mature.

Okay. Now, Your Honor, unless you have any questions, I'm going to turn to written description.

THE COURT: I do have some more on enablement.

***Storer*, the Federal Circuit decision, that was an enablement decision at least in part, wasn't it?**

MR. SINGER: Yes, it was.

THE COURT: And I guess I would like to better understand your position as to its general relevance. But correct me if I'm wrong, did they talk about Mr. Clark there?

MR. SINGER: They did. They did, absolutely, Your Honor. So I think I put it on a slide. I kind of went over. I will go back to it. There it is.

I was talking about the failures of Dr. Griffon.

So in *Storer*, the Federal Circuit said: "To establish enablement of a claim whereby new chemical

compounds are provided for use to treat disease, the application must enable production of the synthesis of the new compounds."

And the Federal Circuit ruled, as the Court knows, that the disclosure in that patent did not so enable the production of the new 2' fluoro down methyl compound in that patent.

It talked about this evidence about Mr. Clark and found it not persuasive as overcoming the failure of the patent specification, which used, again, it's the same thing. In that case, Your Honor, what was argued in support of the enablement was that the method in the patent were known methods of making nucleosides and then a person using and could use those known nucleosides methods with their own knowledge, therefore, come up with the claimed compound.

That is exactly the same thing here. We have their expert saying that the methodologies were known and routine that are in this patent specification and Idenix is saying a person could use those compounds, those methodologies, then come up with a new compound covered by the invention.

So *Storer* is right on point in terms of both just the general background of the law, Your Honor, but also, I mean it, you know, I get it is a different case for a jury and that was an interference, but it talks about the

exact same evidence that this jury heard and the Federal Circuit's conclusions about that. Admittedly a different standard but it is the same evidence.

THE COURT: There was back and forth about closed lists. Is there a material dispute of fact on whether or not the specification of the '597 talks about closed lists?

MR. SINGER: So with respect to written description, I didn't think there was a dispute that the lists in the patent are closed.

THE COURT: Is that a concept that only goes to written description?

MR. SINGER: That is more about written description, Your Honor. It is relevant to enablement, Your Honor, in the sense of what is actually listed there and, of course, doesn't list fluoro, so the failure to enable the fluoro moiety, but, of course, none of the things in the list are exemplified in the patent besides -- as we made besides the OH down, but it's more directly relevant to written description.

THE COURT: Okay. If you would move on to written description.

MR. SINGER: Okay. Let's see. All right. I'll be briefer.

We did move for summary judgment here twice,

Your Honor. And I recognize that we are here a third time arguing about written description in the case, and the jury resolved the issue against us. So I don't want to belabor this. But I think, again, the points here are, these are not disputed points, or at least disputed evidence wasn't presented about these points to the jury.

And I remind the Court once again that in the face of summary judgment what was promised to the Court that would be presented was Dr. Meier's testimony about this aspect of the mimicry and steric hindrance and how that would expand what was disclosed in the patent from the exemplified OH down molecules and the simple lists of possible substituents that are in fact closed to anything. And that a person of skill would be able to do that, and the testimony was not given.

And the deficiency, it is real simple. The patent describes -- and I have here at slide 38 -- specific substituents at the positions at issue.

It excludes certain substituents like 2'-fluoro down.

And it specifically includes -- and I went over this with Dr. Meier in his cross-examination -- it specifically includes that which the Court excluded.

So when you look at the lists, it doesn't include the accused product, the listed fluoro, and it

includes the very thing the Court -- the only thing, the only thing that the Court said was excluded.

And, Dr. Meier, when he went through his exemplary part of the patent, he relied on formula 11. And if you read formula 11, it not only includes hydrogen, Your Honor -- and let me just go right here. It not only includes hydrogen, if you go to the preferred embodiment, the very thing that he relied on, the preferred embodiment is hydrogen.

So you have a patent specification, and the case law says that if you are going to claim the genus, you have got to direct the person of skill to that genus. You don't just kind of get to pick and choose. The jury instructions in this case was apt, cited in our brief, about blazemarks. You don't just get to pick and choose substituents. That is number one.

And then if you are going to claim something that is broader than what you do, you better have disclosures that shows that that is in fact what is claimed.

And you just don't get there from the list in the specification.

And you asked me, was there any real material dispute?

And here is Dr. Sommadossi:

If you look at the '597 patent, there is no

disclosure of a 2' up fluoro down methyl nucleoside?

Correct.

So I don't think there is any real dispute about what is missing from the '597 patent.

Your Honor, I have spoken plenty about both of these issues. I do want to reserve some time to respond to Idenix's argument. Absent any further questions, I'll sit down at this point.

THE COURT: Not at this time. I'll give you a chance on rebuttal.

MR. SINGER: Thank you.

THE COURT: I'll hear now from Idenix.

Good morning.

MR. GRIFFITH: Good morning. I have handed a set of slides up to the Court.

THE COURT: I have them.

(Slides passed forward.)

MR. GRIFFITH: Let me see if I can get our slides up.

All right. May it please the Court, Idenix respectfully submits that Gilead's JMOL motion should be denied, and I'm going to just be addressing the enablement, written description portions today. Ms. Parker will address the damages portion that will come later.

Your Honor, as your questions earlier today

suggest, the posture of this case matters.

The jury has rendered a verdict in Idenix's favor on the defenses for which Gilead seeks JMOL. It was a full and rich trial record. And Gilead bears a heavy burden to have the verdict overturned.

We had a nine day trial, 27 witnesses, four technical experts, 179 exhibits.

Gilead bore the burden on these defenses by clear and convincing evidence, so a high standard, and now is not the time to reargue the evidence. And I believe that is what is happening here.

This is the standard that Gilead has to show. They have to show that the record is deficient on the minimum quantum of evidence to sustain the verdict. The only reasonable conclusion could be in its favor. All logical inferences have to go Idenix's way and all conflicts in the evidence have to be resolved in Idenix's favor. And we can't disturb the credibility determinations of the jury or substitute our own resolutions of conflicting evidence for that of the jury.

Here, the record is not critically deficient of the minimum quantum of evidence to sustain the verdict. And in that regard, Judge Bryson's *UroPep* decision and Judge Robinson's *Amgen* decision -- both denying JMOL after a full jury trial -- are instructive on these intensity factual

issues with competing evidence. That we have in this record. Judge Bryson, I would note, actually sat on the *Wyeth* panel.

Let me start with enablement.

THE COURT: So let's talk about enablement. Is it correct that I've never been asked to determine any genuine issue of dispute on enablement.

MR. GRIFFITH: Yes. They did not file a motion for summary judgment on enablement.

THE COURT: So if it turns out there are no genuine disputes of material fact, what is the legal standard that I would apply?

MR. GRIFFITH: It's essentially the same as the summary judgment standard, but the record is different. We have the trial record here, which is much more substantial than one typically has in a summary judgment motion, but the question is whether, as we discussed in the previous slide, viewing all of the evidence in the light most favorable to the plaintiffs, drawing all inferences in favor of the plaintiffs, can the decision on that only go one way. Could no reasonable jury reach the conclusion in favor of the plaintiffs? But the procedural posture does matter because the jury has heard this evidence and has gone in favor of the plaintiffs. So we have a lot more information here than one typically has on a summary judgment record.

THE COURT: So you have quite a lot of slides here and you're going to have plenty of time to go through them, that's fine, but just as a preview, give me an idea of what you see as some of the genuine disputes of material fact with respect to enablement.

MR. GRIFFITH: Yes. And the easiest way for me to do that, Your Honor -- for some reason, I'm not getting a reaction here -- would be to go to the *Wands* factors.

Well, this is fine. Could we go to the slide that has the jury instruction? I'm not sure what's happening with the clicker.

These are the fact issues, Your Honor, and this is how the jury was instructed, and both parties jointly submitted this jury instruction. This was our joint proposal. And so the jury took these *Wands* factors. Both sides submitted competing evidence on each and every one, how much experimentation would be necessary to practice the full scope of the claim, to synthesize 2' methyl, how routine was such experimentation, and does the patent disclose working examples, the amount of guidance, the nature and predictability of the field, level of ordinary skill, and the scope of the claimed invention.

I think maybe on level of ordinary skill they may have agreed with us, that it was a very high level of ordinary skill, but -- and, indeed, all the witnesses who

testified in here, Your Honor, generally speaking, for our scientific witnesses, they have pretty impressive scientific backgrounds.

So No. 6 goes Idenix's way and all of the others had conflicting evidence on each and every one. And let me try this again. There we go.

It wasn't just that there are these fact issues, but the jury was also properly instructed to weigh the fact issues. No one of the *Wands* factors is dispositive. It's an intensely factual inquiry that was put to the jury and which they resolved, making their credibility determinations and weighing the evidence as they were instructed to do.

Now, let's talk a little bit about guidance from the patent, which I think was one where a lot of evidence was submitted. Again, it was conflicting evidence.

Dr. Meier testified that the 2' methyl feature is the key feature of the ribonucleoside in this claim, a very different situation from *Wyeth* and *Enzo*, both which were so heavily relied on by Gilead where the patents did not identify the key technical feature, the key novel feature of the claim. Those patents did not provide this type of guidance. The patent informs on the mode of operation, something absent from the *Enzo* patents. The enzyme that the compound in *Wyeth* acted on was identified in

the patent, but in *Enzo*, that was the -- the mode of operation was missing.

The jury was entitled to credit this evidence in favor of Idenix. This was some of the portions of the specification that described that the enzyme acts on the HCV polymerase, the NS5B polymerase.

Now, they are rearguing the evidence and saying it just says "may" and we don't know really what it was acting on, skilled artisans wouldn't have understood that it was directed to this, but our expert quite clearly testified that they would understand, and that they precisely understand that it was working on the HCV polymerase.

THE COURT: Now, in the portion and for record, you were showing me the same excerpt that was showed by Gilead. It immediately goes on to talk about the screening and at least implicitly making. What's the record on whether you need to make and screen these in order to understand which ones are within the scope of the claim?

MR. GRIFFITH: Well, certainly, to practice the invention, one has to make the compound. That's a given. But this patent provides guidance to the skilled artisans, that that will certainly work. We have Gilead's concession today that it is enabling with respect to 2' methyl up, 2' hydroxide down, and the base unspecified, notwithstanding that the skilled artisan may have some strikeouts when they

try a base, that it doesn't work. But that's not undue experimentation.

So we have the concession that that sort of modification and that sort of testing and screening is routine. They said the patent is not enabled because of the fact that if one tries bases besides the four natural bases that are exemplified in the illustrations in the patent and also in the data, that doesn't de-enable, dis-enable the claims.

But would one have to do some screening? Certainly. Sometimes one would have to do screening. You wouldn't have to do it if you use, for example, the working examples in the specification, the skilled artisans might do it in the last, but you wouldn't have to. I think there were probably other substitutions, many substitutions that one would not have to do screening on, which are described in the specification.

Well, let me go to it. And this is just another portion of the specification that says for the preferred embodiments, you use the polymerase assay. So it was, again, emphasizing the importance of HCV polymerase, the NS5B polymerase.

Synthetic routes are described. We may come back to that in a bit, but as well, the patent describes how to make pharmaceutically acceptable salts and prodrugs at

various positions on the sugar. Columns 39 and 40, I think maybe 38 to 40 actually get into that in some substantial detail. There was -- it's described as being standard procedures well-known in the art. The same admission actually is made in the Clark patent itself, and Dr. Schinazi testified that these sorts of, this sort of chemistry on these type of molecules is easy. He called prodrugs easy, so that's putting non-hydrogen substituents at various portions of the molecule.

Now, the patent has described other options that one has and these are non-limiting options. They call it a closed list, but there's no requirement that a patent list all of the species that can be used with the invention. And in that regard, I saw on the slides that this was described as specific exclusion. And I think some of the briefs of Gilead say that our witnesses testified that, for example, most notably fluorine at 2' down was specifically excluded. But it's not specifically excluded. It's not -- it was omitted as a specific example of an option at 2' down, but there's no statements in this patent or anywhere to the effect of, stay away from fluorine at 2' down.

THE COURT: It's undisputed, however, that the '597 patent nowhere expressly disclosed fluorine as a 2' down position; correct?

MR. GRIFFITH: As a specific example, that's

correct, Your Honor.

THE COURT: Is it also undisputed that fluorine is a halogen?

MR. GRIFFITH: It is a halogen.

THE COURT: And is it also undisputed that other halogens are expressly disclosed as candidates for the 2' down position?

MR. GRIFFITH: Yes, they are.

THE COURT: And it's also undisputed that you need more than 2' methyl up to cure HCV. Correct?

MR. GRIFFITH: You have to have the whole ribonucleoside, but the 2' methyl feature is, as witness after witness testified, the key feature to this invention. It has to be a ribonucleoside. So that's what the, the importance of identifying the target, the NS5B polymerase, was. It told the skilled artisan that you want to use a ribonucleoside on this.

THE COURT: But not all 2' methyl up ribonucleosides will be effective to treat HCV. That's undisputed; correct?

MR. GRIFFITH: That's correct. It's possible there may be a 2' methyl ribonucleoside that will be inactive.

THE COURT: Is it undisputed that nucleoside chemistry at the pertinent date was highly unpredictable?

MR. GRIFFITH: It is absolutely disputed.

THE COURT: Okay. Tell me where that's disputed.

MR. GRIFFITH: Let me check just a second, Your Honor. I will get the slide to work. 26. This is fine. 33. Then I will move back to 26.

Nucleosides had been used to treat viral diseases before this invention came around. The chemistry related to the science, exploded in the 1980s, as testified to by Dr. Meier, and the principles were used for various viral diseases. If I can go back to 26.

There were a lot of synthesis procedures, synthetic routes and methods known at the time. This is from Dr. Meier. And you could go to the literature and take it and use it. There was a lot of information available. He testified it was routine experimentation to make nucleosides. There's even -- we heard some argument this morning about the most you could do is make two or three a month, I think was the argument, and that was Dr. Secrist's testimony, and that was -- he was talking about what chemists did in his laboratory, whether that was the most they would be capable of doing in a month. What the precise circumstances were, I don't know. It's inconceivable to me that you couldn't attach different bases, do different -- by the way, all of those they count as different molecules,

this is the way they get to billions of compounds. You could attach to the bases. You could do a mono, di, triphosphate. You could add, you could make salts. You could make prodrugs.

Mr. Clark testified that his reaction for doing 2' methyl 2' fluoro was 15 minutes, that reaction. So could more, could one synthesize many nucleosides and ribonucleosides in a short period of time? Sure. And this testimony, the routineness of it totally supports that. More than that though, Your Honor, Your Honor may recall that you didn't always have to synthesize the compound. So when Dr. Sommadossi and Professor LaColla came up with the invention, so they were doing research on the reductase enzyme, and they found, or they found an article describing the structure of the NS5B polymerase, that the structure was very similar to the reductase enzyme. And Dr. Sommadossi knew about, or started looking for nucleosides that would be effective against that reductase enzyme, and he called Dr. LaColla and said, do you have such an enzyme or do you have such a ribonucleoside? He said, let me check.

And so he went and he looked at MD1 in his library. So, and that was the first 2' methyl ribonucleoside that was used for purposes of attacking the HCV.

Now, in addition, Merck had an extensive

library. Dr. Cook, Mr. Cook testified about that. Dr. Storer testified about a substantial library that was present at Pharmasset nucleosides. There was Professor LaColla, as I mentioned. And Dr. Secrist also testified that it was common, I believe, for large pharmaceutical companies to have libraries of nucleosides. That's at transcript page 1728, and Cook's is at transcript page 1336, and Dr. Storer's is at page 657.

THE COURT: So taking all of that evidence and any other in a light most favorable to you, roughly, how many compounds did that add up to that a POSA would not have had to make and synthesize at the pertinent time but could have pulled off a shelf, at least figuratively?

MR. GRIFFITH: I don't have a specific number to give you, but just taking the short period of time that it took Mr. Clark to synthesize to 2' methyl 2' fluoro, and he said 15 minutes, but, you know, let's assume for the sake of discussion, a couple of hours. You know, one can do many in a day and many more in a month.

THE COURT: All right. I think I'm asking a slightly different question. I understand the argument that maybe it's routine and easy to make more, but I think you're also arguing, I think you brought this point up, keep in mind, you don't have to make them all. You don't always have to synthesize them; right?

MR. GRIFFITH: Right.

THE COURT: So taking all of that evidence in a light most favorable to you, all of those libraries you just mentioned and any others for which there's a record basis, does that add up to a hundred, a thousand, a hundred thousand? What could the jury have reasonably concluded on that?

MR. GRIFFITH: I think they could have very reasonably concluded that it was a substantial number for purposes of testing and looking at activity. And then you have that coupled with the testimony about the ease with which assays can be done and with the high throughput for that. 10,000 a month, maybe more. It's thousands per month. They could be done.

So we have a situation where on this evidence the jury could reasonably have concluded that making compounds and testing them was not undue burden in this art, which, by the way, was an art that was accustomed to screening.

So like in the *Wands* case, where screening was -- it was a monoclonal antibody situation, so screening was very common there, and that was pointed out by the Court as being a factor in terms of the nature of the art and the nature of the invention. Screening was sort of an expected activity to be engaged in. So this is not something,

screening is not something, making and screening compounds is not something that skilled artisans here viewed as untoward work, undue burden.

Now, they argued against that. They put in evidence arguing that it would have been a lot of work and that the skilled artisan would not have expected to have to confront this activity, but that's, that was a fact issue for the jury to decide. That is not something to be undone now after they weighed the evidence and weighed their credibility determinations.

And further on guidance, Your Honor, there was argument this morning -- let me go back. There are a couple of points I want to make sure I hit on here.

So Gilead's counsel pointed to some testimony from Mr. Clark about how, that he made regarding how he arrived at this. We had testimony from Dr. Otto, who says that he met with Clark right around the time he was coming up with the idea to use 2' methyl 2' fluoro and we asked him, did he present you with any literature that guided him to 6130, this first 2' methyl 2' fluoro compound. The answer is, well, he didn't say what necessarily guided him to that idea. But he did bring with him to my office copies or portions of copies of a Merck application and a Novirio application.

So the jury could reasonably infer from this

that Novirio application, the Idenix patent application, and this was the specification that is the '597 patent, is what guided Mr. Clark to 2'-methyl, 2' fluoro, and aided him in his synthesis, which he was able to do with ease during this time frame with clearly having Idenix's patent application in hand.

Now, the jury could have credited this discussion. And Your Honor pointed out, I think Gilead's counsel made a point of you have to take the good with the bad with the testimony, but the jury doesn't have to do that. It can credit some testimony from a witness and not credit other testimony.

And so the fact that there is in some instances perhaps conflicting testimony about what things happen and how things unfolded, the jury's job was to sort that out and we can't, we can't unravel that now.

Now, there is another important piece of evidence on this point. And that is that in this time frame, when the '597 patent published as a PCT application, the folks at Pharmasset, scientists at Pharmasset got their hands on it, read it, and they noted that it, it reported on modified nucleoside analogs with potent inhibition of the HCV NS5B polymerase.

So they knew what, they knew exactly what enzyme it was going after. Again, some of their experts challenged

that, but they knew from reading this patent what the target enzyme was.

Now, they also identified one of the classes that are potent inhibitors. And one was 2' modifications, methyl or O methyl. But the methyl class of compounds was pointed out here, and it pointed to just 2'-C methylcytidine as a representative of that class.

So they completely got the importance of 2'-methyl, and that it had the ability, that ribonucleoside had the ability to be effective and active in other forms besides 2'-methyl, 2'-OH.

THE COURT: What is in the patent that the jury could have reasonably thought would have directed one of skill in the art to the 2'-methyl up, 2'-fluoro down?

MR. GRIFFITH: I think, Your Honor, it's the teaching that 2'-methyl ribonucleosides are effective for treating HCV. So this patent taught the genus of those compounds that were effective against HCV. And the skilled artisan reading the patent understood that modifications could be made, and so the skilled artisan could make modifications at 2' down. And they could have credited even Mr. Clark's testimony -- or, I'm sorry, Dr. Otto's testimony as supporting that.

But the point is the patent doesn't have to list every species. It doesn't have to lead you to some

particular species. The genus here, the class of compounds has to be supported, and we don't have to call out every possible species that might be used. And it doesn't have to lead you to one particular one over another.

THE COURT: Okay. But is there anything that would have led one of skill in the art to this embodiment, the one that is now the accused one?

MR. GRIFFITH: Yes. I think the, I think the data, for example, in the patent certainly did that. So that was on the 2'-methyl, 2'-hydroxide. But I think that that skilled artisan looking at that data would have been and could have been led to try other 2'-methyl to other substituents in the down position, one of which could have been fluorine. So as I say, it doesn't specifically say go do fluorine, but it doesn't have to do that. That is not required for enablement. We don't have to enable the infringing product, if you will.

THE COURT: Do you agree you have to enable the full scope of your claim?

MR. GRIFFITH: I do.

THE COURT: So what does that mean here to enable the full scope of your claim as construed?

MR. GRIFFITH: That means that the skilled artisan has to be able to practice within the claim without undue experimentation.

So you can't have -- so in, for example, *Liebel-Flarsheim*, half of the claim was on not having a pressurized jacket and the other half was on having a pressurized jacket. They didn't enable the not having a pressurized jacket half of the claim.

But, broadly speaking, it means that skilled artisans have to be able to practice the invention within the genus.

THE COURT: Do they have to be able to practice without undue experimentation the full scope of the claims?

MR. GRIFFITH: They do, Your Honor. But just to be clear, that doesn't mean that the project here is for the skilled artisan to go out and make every compound covered by the claim. So in most cases -- and that is explained, for example, in the *UroPep* case, but it certainly is not unique to that. In the *UroPep* case, Lilly seemed to be making the argument that enablement requires that every PDE5 inhibitor, a skilled artisan had to be able to make those in a short period of time, go out and make the entire class of compounds. So no one would do that.

So to me, Your Honor, the meaning of being able to practice within -- enable for the full scope of the claim is that a skilled artisan can take this invention, 2'-methyl ribonucleosides, not specific to OH down, and can make those, make such compounds without undue experimentation.

It doesn't mean that they can make them all simultaneously this week but if they wanted, if they set out to try to make a compound, they will be able to do that without undue experimentation.

The *Wands* case, perhaps, is instructive here, and as well as *UroPep*.

So in *Wands*, you had to screen for the monoclonal antibodies. So the class, the class was unlimited. I think they were specific to high affinity antibodies for an HBV antigen. And there is a limitless class of compounds. But the issue there and the issue here as Gilead has framed it was whether it was a needle-in-the-haystack problem to go out and make anything other than specific embodiments that had been described in the patent or deposited with the government at the time.

And what they found there was you had a, I think in *Wands*, a 44 percent success rate. So you would go out and make your hybridoma and it was a lot of work. You had to get animals. You had to inject them and infect them and fuse cells to make the, to screen the hybridomas. Was this going to be a futile exercise for skilled artisans when they did that or would they be able to come up with these monoclonal antibodies in the patent, the high affinity ones? And the answer was they could.

Specifically, in that case it was 44 percent of

the time. The numbers that were involved in that case, it was 44 percent. So half the time, a little bit more than half the time they would strike out. That doesn't mean that the claim is not enabled. You could make various embodiments within the scope of the claim. You set out to do it and you will be able to do it. The patent gives you the tools to be able to do that.

This patent does that. And coupled with the tools that skilled artisans have in their toolbox at the time, so assays, running screening assays was something that skilled artisans have here. They were able to do that. The synthetic routes were not unduly burdensome. This was a well developed science at that point in time.

THE COURT: So I understand they don't, we don't need any one person of skill in the art to have taken the time to make every embodiment, every claimed embodiment. That is part of your argument. I understand that.

MR. GRIFFITH: Right.

THE COURT: Does it have to be, however, that should a skilled artisan have wanted to do that, that with whatever they would know as one of skill in the art plus the patent, that they could make all of those without undue experimentation, all embodiments?

MR. GRIFFITH: I think I agree with that, Your Honor, with the understanding you are not talking about --

in other words, could they go out and make any one of them I think is what Your Honor is asking.

THE COURT: Well, that was going to be the next question. If you want to answer that one.

MR. GRIFFITH: I don't think undue experimentation means you can go out and make every compound covered by a claim without that being a big job, a lot of work, undue work, that sort of thing. I don't think that is correct.

THE COURT: You don't think you have to have enabled any one to be able do that --

MR. GRIFFITH: Right.

THE COURT: -- in order to have that.

MR. GRIFFITH: That's correct.

THE COURT: But how about your question? Does one of skill in the art, looking at the patent and knowing whatever one of skill in the art knows, have to be able to visualize the full scope of the embodiments that are claimed and be able to say, without undue experimentation, hey, I want to get this one. I can do that without undue experimentation.

MR. GRIFFITH: I would say that is roughly the case. I would not say there are never any exceptions to that, Your Honor. You can have improvements on things and so forth.

And so when Apple came out with the iPhone, ten years later, can you come up with some version of it that they wouldn't have been able to make back then? I don't think that sort of thing would defeat the patent, I wouldn't say.

So with that in mind, I think broadly speaking what we're talking about is being able to practice the claim across the claim and not -- so if, you know, the issue would arise here that if there was only one species in a genus that could be made without undue experimentation, that would implicate the question that Your Honor is asking. But I don't think that is even remotely close to being the case here.

That was the issue, Your Honor, in *Wyeth*. And if I may go to that?

THE COURT: Sure.

MR. GRIFFITH: Well, first, Gilead's statement of the holding in *Wyeth* is that "required screening of 'a lot of compounds' ... to find the active species fails to enable the full scope of the claims as a matter of law."

That is not the holding of *Wyeth*.

And in both *Wands* and *UroPep*, there was required screening of a lot of compounds to practice the claim across the full scope.

And so each of these cases has to be decided on their own facts and circumstances in the context of the

level of skill in the art, the predictability of the art or the unpredictability of the art, the level of what is routine experimentation, what isn't at a given point in time. About all of that, and we had much fact dispute about each and every *Wands* factor, we had fact disputes in this case.

But, in *Wyeth*, the problem was the patent -- there were a number of issues that the Court looked at there. The patent was silent on how to modify compounds. It didn't give any guidance whatsoever about, hey, you can make this change, you can make that change. You can do this.

We had substantial guidance on changes and modifications that can be made to the 2'-methyl compound at issue here.

We have issue of contemporaneous guidance that the patent provided to scientists at Pharmasset. This patent was absolutely crucial to them. They took this 2-methyl compound and ran with it.

There were assays here. Assays could be done on thousands of compounds routinely. And in *Wyeth*, for one single compound, it took weeks. That was just for one.

The rapamycin art was unpredictable and poorly understood.

We had evidence here of synthesis of nucleosides

was certainly predictable and well understood, and use of nucleosides to treat viral diseases was known.

Now, Gilead's counsel had testimony from Mr. Meier that he put up saying use of, the use of nucleosides to treat HCV was in its infancy in 2000.

But it wasn't that the skilled artisan was without information about using nucleosides for viral diseases and that sort of thing. And each of the scientists who testified or many of the scientists who testified in this case indeed had experience on just that, on using them to treat HBV or HIV and even had patents in those areas before this.

THE COURT: But is it undisputed that the use of nucleosides to treat HCV was in its infancy at that pertinent date?

MR. GRIFFITH: I believe that it was in an early stage at this time. Then the 2'-methyl ribonucleoside class gave predictability to that field, and that is what the Pharmasset scientists latched on to.

THE COURT: And I can find Dr. Meier saying that, that the 2'-methyl gave predictability?

MR. GRIFFITH: He testified to that being the key feature of this compound.

THE COURT: But does he testify that, therefore, all of the, whatever you put it, the other substituents,

whatever they are, it's predictable, whatever their activity would be?

MR. GRIFFITH: He testified that it would be not undue experimentation to make modifications at the other positions following the guidance in the patent, and that you would be able to do that and have an effective compound. So, yes, in that sense.

And I guess I would point further, Your Honor, to the Pharmasset evidence, for example, the grant application saying the 2'-methyl class of compounds is a potent inhibitor of HCV. That is a clear statement of they believed it predicted effectiveness.

Again, as Gilead's counsel noted, you know, could you find a base that wouldn't be active with the compound? Yes, you could. That is possible. But basically this class of compounds honed you in on that which was effective for treating HCV. And, indeed, 11 out of the 12 ribonucleosides -- and there was testimony by I think Dr. McHutchison to this effect. He noted the compounds that had gone to market, or, I'm sorry, into clinical trial to treat HCV, 11 of the 12 ribonucleosides were 2'-methyl compounds. 11 of the 12. So this compound became the gold standard for this area of research.

Skilled artisans here, as Dr. Secrist testified, were used to working with large classes of compounds. So

this is not a foreign idea to have, you could have different substituents at different positions. You could have salts that you would use here, prodrugs that you would use here, changes that could be made to this or that. He and both Dr. Sofia also testified to, yes, we worked with large classes of compounds.

THE COURT: Before you move on from that slide, I want to talk a little bit more about the amount of time. As you know here in *Wyeth*, they found that it would take weeks to test even a single compound. What is in the record here about how long it would take to test all of the embodiments of the claim here?

MR. GRIFFITH: The record is that you could do, you could test tens of thousands in a month.

THE COURT: And how many embodiments are there within the scope of this claim?

MR. GRIFFITH: I don't have a number to put on that. Dr. Meier did not put a number on that.

What I would note, Your Honor, is that in terms of testing compounds, I mean he characterized it as a relatively small class.

Now, that within that, if you are testing, doing assaying, and then in conjunction with Dr. DeFrancesco, you could run a lot of assays in a month.

So, again, you don't have to -- it's not a

matter here of being able to find, for the skilled artisan to go out and find every one. The question is are they going to, as they would in *Wyeth*, have a high rate of futility if they were to do that?

And there is no evidence in this record that the skilled artisan practicing the '597 patent, making 2'-methyl compounds, applying, for example, formula 11, would have -- the evidence was not introduced that a substantial portion of that would be ineffective or would not work.

Now, they bore the burden on this defense. It was on Gilead to come forward with evidence to convince the jury by clear and convincing evidence that this claim was not enabled, and we don't have the type of evidence that they had in *Wyeth*, where you had one compound, one compound, no suggestions or teachings on how to modify that compound. They have that here, lots of teaching about how to modify it using different bases, monos, dis, triphosphates, various substituents suggested, identified as options in the formulas. Prodrugs, salts, so forth. All of that is included here. None of that was present in the *Wyeth* patent.

THE COURT: If the only conclusion for the record here is that it would take at least weeks for one of skill in the art to make and have in hand any particular embodiment of the claims, would that favor a finding that

the experimentation was undue?

MR. GRIFFITH: I would say not, Your Honor. You know, I mean, we are in the drug development area here, and so I think that -- I mean, nobody put a precise timeline on exactly how long it has to be, but in terms of the volume of experimentation that scientists do in this area, all of that in terms of what, you know, what they did and assays they ran and so on and so forth was indicative of, you could spend time on this. I mean, there was no -- you know, in the *UroPep* case, they commented on, look, it may take time to make a molecule according to this patent, but that doesn't change that there's not undue experimentation there. There were ways to do it, it could be done.

And coming back to, this sort of relates to your Honor's question about enablement versus full scope. So Gilead has pointed out that in *UroPep*, there were, I think they said a hundred known selective PDE5 inhibitors, so there were some disclosed to the patent. I don't believe in the patent they were specifically identified as selected PDE5 inhibitors, but the Court said, skilled artisans would know that I think maybe it was four of them would be selected PDE5 inhibitors.

Then there were others that could be -- that were known, not mentioned in the patent that were known. But the class was alleged to be billions, and Judge Bryson

found that whether it was billions or not, it was a very large class. But that didn't change that. You could still do your screening activities and find a compound that -- you know, that would work, not just the ones that were known. All right.

So it's a large class of compounds that you would have to screen to find that which would work, but that -- and to do that across the full scope of the claim there. So the claim wasn't limited to just the 100 that were known.

So that's the point. They argued that you didn't have to screen. You could just use one of the hundreds. To practice the invention for the full scope, you would have to do some screening. No prohibition on that and it would take some time.

THE COURT: All right. But here are the comparable numbers. I think the best case for you are the structural limitation is satisfied by billions of compounds, and at best, you disclose four or maybe six that meet the functional limitation.

MR. GRIFFITH: I don't agree with that.

THE COURT: Is that a fair understanding of the record?

MR. GRIFFITH: I don't agree with that, Your Honor.

THE COURT: Tell me where that is wrong.

MR. GRIFFITH: First, on the billions of compounds pointed, Dr. Meier -- if we could go to that slide -- disagreed that it was that broad. Again, this is a *Wands* factor, the scope of the claim.

Dr. Secrist testified that it would be billions and Dr. Meier said, no. Reading the patent and looking at it as a whole in the way a skilled artisan would, it would be a significantly smaller number than that.

THE COURT: Well, I meant to say first with respect to the structural limitation, just structural limitation, what you could put in each of the different 2', et cetera, positions.

MR. GRIFFITH: Well, I think that's what Dr. Meier was talking about. In other words --

THE COURT: What did he testify to about how many --

MR. GRIFFITH: Significantly smaller.

THE COURT: Significantly smaller than billions?

MR. GRIFFITH: Yes.

THE COURT: And so what best case could the jury have decided was the number of compounds, the smallest number of compounds that would satisfy the structural limitations of the claim?

MR. GRIFFITH: I think the jury could reasonably

have concluded that we're talking about some number of thousands.

THE COURT: Because that's significantly smaller than billions?

MR. GRIFFITH: Yes. But it's not just that, Your Honor. I mean, Dr. Secrist admitted that you don't check your common sense at the door, and so I think what we see here when Gilead is getting to billions, what they're doing is, they're, for example, they're counting OH at '5, monophosphate of '5, diphosphate of '5, triphosphate at '5, all separate compounds.

So that's four compounds there, and then there's four bases, so that's 16 compounds, and they are just doing math here. That becomes an issue, Your Honor, when the patent describes, for example, various prodrug substituents and salts that could be used at various positions. That you're not going -- if you do in the course of going out to, if you do some screening, you find, let's say, one active compound and one inactive compound, you are not going to go make a prodrug of the inactive compound, but in Dr. Secrist's world, all of that counts, because mathematically, that's possible. That's all mathematically possible that could happen with that claim.

THE COURT: But he says that because there's nothing in the patent that excludes that from being put at

each of those positions, just in terms of the structural limitations. Isn't that correct?

MR. GRIFFITH: I think he says that because it drives the number up. I don't think -- for example, if the patent does teach you can put prodrugs at '5, at 3', at 2', you can put them at different positions. So in his world, you may put them at all three positions simultaneously, and I don't think Dr. Meier is going to that type of level. He's taking a more practical approach. So he's recognizing that skilled artisans, when they look at the things that are identified here, yes, you have these options, but you are not necessarily going to try them all at once just because you theoretically can. You could make a prodrug if you wish, but you are not going to put prodrug moieties on all at the same time. And you don't have to go out and make multiple prodrugs. You can if you want to try to optimize and find the best, but that is not required to practice the patent.

And this is an intense factual dispute between these two witnesses as to the breadth of the claim and exactly how much. For skilled artisans in this field, how much work it would take them to, applying the teaching of this patent, make compounds according to the patent.

THE COURT: All right. Well, then we had -- I think you agree with this. There's a structural limitation,

which we've been talking about. Then there's the functionality limitation.

MR. GRIFFITH: Right.

THE COURT: It has to be effective to treat HCV. Right?

MR. GRIFFITH: Right.

THE COURT: So in your view, how many embodiments that meet both of those limitations so they have to be effective to treat HCV are disclosed in the patent? A better question: What could the jury have reasonably found are the number of embodiments that satisfy both the structural and functional limitation of the claim?

MR. GRIFFITH: Well, they could have concluded that there are many that a skilled artisan could make. Skilled artisans, this is not a large class of compounds, but nonetheless, the numbers are such that it could be a good many. So, for example, so they've agreed today that 2' methyl 2' OH, anything in the base position is enabled, and there I think there was 260 compounds that Dr. Gosselin had logged. Dr. Seeger had identified 38 of them that he said were inactive. So he didn't give us the numbers for, in his opinion, the total active versus inactive, but what he showed to the jury was, 38 bases out of 260 that he said were inactive. So, I mean, there's -- you know, there's a good number of compounds right there.

Dr. Sofia, when he made his prodrugs, he was working on the prodrugs, he made 140, on that order, of prodrugs, again, trying to optimize and find which is best.

THE COURT: And there was evidence from which the jury could have reasonably found that all of those were effective to treat HCV?

MR. GRIFFITH: Yes, Your Honor. I mean, the compound was certainly active, and he had his -- they introduced his patent into evidence, and it has -- well, that was one that has a billion, million compounds if you count the way Dr. Secrist does. It has lot of options. I think it had 80 or so examples of prodrugs that were active. He never testified that any of the 140 were not active, so the jury could have reasonably concluded from that evidence that there are a good number of compounds coming from a variety of ways, there are a number of changes that could be made that are effective and that are active here, and that they did not see evidence that there was a -- the evidence was not introduced to show that there was a substantial portion of the examples and options and so forth illustrated in the patent, that they were not effective.

So this is, as I said, this is not a -- they characterized it their brief a needle-and-haystack situation, but there is insufficient evidence here that that is what this is. You only get there by doing this

theoretical mathematical approach that Dr. Secrist advocated for. Dr. Meier said that that is not the way skilled artisans would approach this patent, and the jury could have resolved that fact issue in favor of Idenix.

Your Honor, may I speak to the 2' methyl, 2' fluorine synthesis issue?

THE COURT: Sure.

MR. GRIFFITH: And if there are any other questions Your Honor would like to ask about this breadth of the claim?

THE COURT: There probably are, but I will ask them. You move on as to what you want to move onto.

MR. GRIFFITH: The points I want to make here, Your Honor, are that -- so the argument is that it would be undue experimentation for the ordinary skilled artisan to synthesize 2' methyl, 2' fluro-based on this patent. A detailed recipe for every species does not have to be put forth in the specification. That's not the law. General synthetic routes are disclosed.

I looked at -- I showed this to Your Honor earlier. The jury could have reasonably concluded from Dr. Otto's testimony that Mr. Clark was guided by, instructed in his synthesis work by the '597 patent. It was the PCT version of it, but it was the same specification.

He said that he used DAST, a well-known

fluorinating agent, so this was something that skilled artisans knew about. He testified that it was -- it could be done quickly, about 15 minutes. He thought he succeeded in his first try. This is not undue experimentation. This is not needle in the haystack.

And Mr. Clark had below level of ordinary skill in the art experience, so he was just a Master's in chemistry. The testimony was the PMDs, it could be a lower degree, but it would be some number of years of experience. Mr. Clark was below that ordinary level of skill.

Now, so the jury could have reasonably concluded from the Clark evidence that it was not undue experimentation to make 2' methyl, 2' fluoro with the knowledge of the '597 patent in hand.

Gilead submitted competing evidence, Griffon evidence, from which it argued that Idenix failed when trying to make this compound, and that that indicated that the skilled artisans would find this difficult to do. And even so, Dr. Griffon did testify that he thought he actually did arrive at an effective route, but that he didn't realize it at the time. And the reason, the testimony on that was that he didn't look at all of the spots when he ran his TLC, so he looked at, I think it was one spot, and there were other spots on the plane that he should have looked at.

And, but this was an intensely -- intensely factual dispute that the jury was entitled to weigh the evidence on and reach its conclusions based on its credibility determinations, and there's no outcome here that is required as a matter of law.

***Liebel-Flarsheim* is not on point. That is the pressure jacket and non-pressure jacket case. The claim covered both, but the patent criticized non-pressure jacket designs. Now, they emphasize that in *Liebel*, the inventors, or at least the engineers at the inventor's company struggled to make or failed to make the design without the pressure jacket, but the Court pointed out that it was -- it was that evidence coupled with, coupled with the criticism of that design in the patent that led it to conclude that there was a failure of enablement there. And we did not have competing evidence there like we have here in Clark.**

Now, they point out, well, the infringer there made it, but that's -- it's not the circumstance we have here with Clark walking into Dr. Otto's office with specification in hand back in the relevant time period and so forth. There was nothing comparable to this. And as I said, they emphasized the teaching away, which is not present in this patent.

And then they rely on the *Storer* decision, but I

have not heard argument from them, and I don't think there is one that collateral estoppel or some other legal doctrine mandates that the outcome in *Storer* be applied here. It's not. It was a different patent, different proceeding, different burden of proof, and so forth, and so it doesn't mandate the jury have reached the conclusion that the Patent Office reached in connection with that patent in that case, which was not the '597 patent.

THE COURT: Did the Federal Circuit have in front of it the evidence about Mr. Clark that you introduced at this trial?

MR. GRIFFITH: No, Your Honor. Now, we had the Clark patent and we had some evidence regarding that work, but we did not have the testimony from Mr. Clark that we showed to the jury, and there was a reason for that. That testimony was procured in part in this case and in part in connection with the 1782 petition in a foreign proceeding. And Gilead demanded in connection with that 1782 petition in discovery, that deposition of Mr. Clark, that we agree to a protective order. A protective order was entered at their insistence, that the Clark deposition could not be used in the interference proceeding.

So they were concerned that we would be using 1782 discovery to get discovery in the interference. They said that would be foul play. The Judge entered a

protective order. We weren't permitted to use the Clark depositions in the interference. Likewise, the Dr. Schinazi testimony regarding the importance of 2' methyl were not permitted to be used in that proceeding. Dr. Storer testified and all of this went to the reaction to the '597 patent at the time and it also went to synthesizing 2' methyl 2' fluoro.

Dr. Griffon's further deposition in this case, or we showed the testimony there, was not available at the time.

The Pharmasset grant applications, where they relied on the '597 patent, was not in evidence there.

So it was a different evidentiary record and there were various reasons for that, but it was not the same record. And that in and of itself is a reason why that case cannot be applied here. Likewise, different burden of proof. And under *Baxter* -- I'm sorry. If this is the portion of *Baxter* saying it's a different evidentiary record, the Patent Office can reach a different conclusion from the District Court, and this is what happened in Baxter.

They also said the same thing with respect to burden of proof, and they as well, Your Honor, said that even if you had the same evidence, it could come out, same patent, same patents. This is a different patent, different

evidence, but they said even if you had the same patent, same evidence, you could come out with a different conclusion just because of the different burden of proof.

Here, the jury had competing evidence on this factual issue, whether under the *Wands* factors it would require undue experimentation to take 2' methyl, 2' fluoro. All the testimony about synthesizing nucleosides had been happening for decades. I think Dr. Secrist said more years than I can remember.

So this is about synthesis. So synthesis went back a long time. The jury could weigh that evidence, predictability, could weigh that evidence. I understand that Gilead made arguments to the contrary, but they did not have to credit those arguments. They did not have to credit the testimony going Gilead's way. They could have credited Idenix's testimony, and that is what they did. And they found in favor of enablement.

Now, on written description.

I want to, before I get to written description, Your Honor, I wants to go back to, real quickly, the *Wands* factors. And if I could back to slide, I think it's around 13 -- or, you know, let's go back to 13.

All right. We did talk about this one.

The patent pointing to what enzyme this is working on. This was a fact dispute. They disagreed with

it.

Synthesis roots are taught in the patent.

How to make representative compounds.

And the formula 11.

And Dr. Meier went through all of this.

Dr. Secrist testified that you don't make foolish decisions or foolishly try to make anything just because you can.

This is the Clark testimony, the grant application.

Now, were there working examples? So that is one of the *Wands* factors that the Court instructed the jury on. Yes, there were. There were here. There were not in *Enzo*.

There was data for the working examples.

How routine was any necessary experimentation in the field?

This was a lot of synthesis procedures were known.

Synthesis was not in its infancy.

Screening compounds was routine.

The quantum of experimentation necessary. Screening thousands was known.

You could synthesize quickly. You didn't have to be slow.

The nature and predictability of the art.

This is where it was commented on that this was not the first nucleoside to treat a viral disease that came around.

All of these were factual evidence that the jury could have credited and specifically following the *Wands* instructions that they were given by the Court and they could have reached these conclusions on these fact issues in favor of Idenix.

It's common to think about large classes of compounds in this field, as testified to by their expert, Dr. Secrist.

There was -- and Gilead's counsel mentioned this in his presentation. This is the Storer testimony about we would look to mimic structures at 2' down, and Gilead's counsel criticized him because he said, well, this wasn't specifically tied to the patent, but this was back in 2001 when he started at Idenix and it was exactly in this field, exactly on these sorts of compounds.

So it's completely relevant to what persons of ordinary skill in the art do. The jury was entitled to credit this evidence.

THE COURT: Did anybody ever say what one of skill in the art, though, would have known about that mimicking?

MR. GRIFFITH: Yes. Dr. Storer said that one of the tools they had was to use, to look for mimics of OH at the 2' down position.

And he commented, fluorine is a small electronegative atom, so it doesn't introduce a large steric demand.

THE COURT: I think part of the argument was he is not necessarily one of skill in the art, and he is not necessarily testifying about one of skill in the art, what was skill in the art that the expert would know at the time.

MR. GRIFFITH: They could have made that point to the jury. They could have tried to attack the credibility of that testimony by that sort of criticism, but at the end of the day, this is for the jury to decide. This was not irrelevant, and when it came into the case, it was not objected to as being irrelevant.

Those are criticisms they were free to point out to the jury, but it doesn't establish as a matter of law that this is something that a person of ordinary skill in the art would not have done.

On the contrary, it seems pretty clear that a person of skill in the art would have done this, was doing it. The level of skill is very high.

And then we talked about the scope of the claimed invention and the differing testimony on that.

This is, on every single *Wands* factor, we put on evidence, really a mountain of evidence on each one, and established that following this Court's jury instruction, the jury should come out in favor of Idenix on enablement.

And having put in certainly far more than a mere quantum of evidence on each and every *Wands* factor, I think this Court needs to actually find on each and every *Wands* factor that they found in Idenix's favor. This was a judgment as a matter of law. We're not at the closing argument stage.

So having done this, it is really a mountain of evidence, the jury could reasonably have reached a verdict in favor of the plaintiffs on enablement.

THE COURT: Well, before you go back to written description, let me ask you some more questions.

I think on the enablement question, as I understand it, it is Idenix's characterization of their invention that the key to it, the critical part is the 2'-methyl up; correct?

MR. GRIFFITH: Correct. The 2'-methyl ribonucleoside structure.

THE COURT: So does that mean that at least all compounds with 2'-methyl up ribonucleosides have to be enabled in order for this patent to be valid?

MR. GRIFFITH: No. No, it does not. And so,

for example --

THE COURT: So why is that? Why does the one not follow from the other?

MR. GRIFFITH: Well, because that is what *Wands* tells us. So you can have some amount of strike outs in this in connection with the patented invention and that does not disenable a claim. The success rate in *Wands* was 44 percent.

Gilead's counsel agreed that a 2'-methyl OH down ribonucleoside is enabled, and that this claim, if it was limited to OH at 2' down would be enabled even though their own witness found 38 ribonucleosides with that formula that he said were not active.

That amount of failure does not create undue experimentation. It's very common, Your Honor, to have inoperable embodiments within the scope of the claim that is not fatal to a claim.

THE COURT: So your view is in order to be enabled, it is not necessary that this patent teach those skilled in the art how to make and use the full scope without undue experimentation of all embodiments that have the 2'-methyl up? It is the key to the invention but we don't have to tell a person of skill in the art in the patent how to make and use all of those embodiments?

MR. GRIFFITH: That is not what I'm saying, Your

Honor. And I apologize if I'm unclear. Let me try again.

You do have to enable for the full scope of the claim. I agree with that. The patent is required to enable using 2' ribofuranosyl nucleosides, methyl up, nonhydrogen down, to treat hepatitis C, to be effective in treating hepatitis C.

What I'm saying is the fact that when the skilled artisan, following the teachings of this patent, sometimes makes a 2'-methyl compound that is inactive, so it is a strike out, that does not mean that the claim is not enabled. You are allowed to have some amount of failure. That was exactly the circumstance in *Wands*.

THE COURT: Okay. In order for the claim to be enabled, does the patent have to tell us somewhere that what is key or what is critical is that 2'-methyl up be used at the 2' position?

MR. GRIFFITH: I don't know that it has to, but the evidence, the overwhelming evidence in this case is that it did. And Dr. Meier so testified to that.

But it wasn't just Dr. Meier. Those Pharmasset scientists pointed right to the 2'-methyl feature. And they didn't say, you know, it's the 2' in combination with OH down or some other thing. They pointed to the 2'-methyl feature. So we have that circumstance here.

Now, I get that they argued and their experts

disagreed with Dr. Meier's opinion on that point, but that is a fact issue in terms of what skilled artisans, the ordinary skilled artisan would understand and appreciate from reading this patent. That is part of the guidance aspect of the *Wands* factors that the jury assessed, weighed, and came out in favor of Idenix on.

They didn't have to come out in favor of Idenix on every *Wands* factor, by the way. As the Court instructed the jury, they can -- no one is dispositive, and the jury's duty was to weigh the *Wands* factors and size them up on their own and reach their conclusion based on their weighing of the evidence. It wasn't that one trumped any of the others or was controlling over the others.

THE COURT: In the cases, what, if you know, is the longest amount of time that courts have looked to for how long the experimentation would take and still said that that claim is enabled?

MR. GRIFFITH: I'm trying to think about it. I mean in the *UroPep* case, they certainly said it can take a lot of time without quantifying specifically how much it would be.

Now, again, if you select one that is identified in the patent or, you know, of the PDE5 inhibitors, then that would be quicker than if you try to make some embodiment that is not depicted but in *UroPep* they said it

can take a long time.

That it's not the guidepost.

THE COURT: Dr. Sommadossi testified there is no disclosure of the 2'-methyl up fluoro down nucleoside disclosed; isn't that correct?

MR. GRIFFITH: There is no -- right, that specific species was not called out in the specification, that's correct, as was discussed in claim construction. And at the time, they said that constituted a disavowal. They said that was a specific exclusion. And the Court found that that silence on that was not a specific exclusion, was not a disavowal. This is not a *Liebel-Flarsheim* situation where it was a criticism of the jacketless design in *Liebel-Flarsheim*. Here, there was no criticism of using fluoro at the 2' down position. None.

THE COURT: Okay. You can move on to written description, if you want to.

MR. GRIFFITH: I guess, you know, I'm thinking about your question, Your Honor, about, I mean I just don't think there is, under the *Wands* factors or under any other of the Court's cases, any hard and fast rule about what is the maximum amount of time.

If I go back -- and it is always dangerous to think out loud but I'm going back. If you go back in time to the invention of the automobile, and we're talking 1800s

at some point in time, no doubt for someone to take that patent and construct an automobile would take some substantial amount of time. It just would. Putting an entire automobile together by hand would take time. That doesn't mean it would be undue experimentation. That is why we have these *Wands* factors that look at the particular context of the art and have the experts testify about that and deal with fact issues in that fashion.

On written description, Your Honor, I'll keep my comments brief. I promise.

THE COURT: I know I have taken a lot of your time with enablement.

MR. GRIFFITH: And that is fine.

The issue has been decided here, twice actually. And the Court, in denying their motion for summary judgment, said the fact-finder could credit Dr. Meier's opinion and analysis and find as he opines that the inventors had possession of the claimed invention.

The record also contains Gilead documents which was, for example, the grant application, but not just that, from which a reasonable fact-finder might conclude that Gilead and/or its predecessor Pharmasset recognized that the inventors of the patents-in-suit were in possession of their claimed invention.

The fact-finder here, the jury, did reasonably

credit Dr. Meier's opinion and other evidence and find that the inventors had possession of the claimed invention.

And evidence that the Court pointed to as showing a fact dispute to be resolved by the jury was the disclosure that the invention of nucleosides may inhibit HCV polymerase activity. That is what is the target.

The patented formulas, the Court noted. The patent data was pointed out. And we introduced evidence on all of those things.

We introduced the Gilead documents that the Court pointed to. Dr. DeFrancesco commented on those, the significance of those to a virologist.

The specification. The Court pointed out the spec shows the inventors were in possession of nucleosides with certain structural characteristics that were effective to treat HCV. We introduced that with Dr. Meier. They haven't denied any of this testimony was submitted.

And the Court, in pointing out the fact dispute, noted, for example, that the Gilead documents were an independent reason for denying the summary judgment motion, as it is here for denying JMOL.

This is really where their big distinction comes for the written description issue. And that is that they say Dr. Meier didn't come forward, didn't come through with this particular testimony. He testified that the inventors

had possession of a definite class of compounds ... useful in the treatment of HCV. But they say he didn't finish up with the naturally occurring substrate of the HCV polymerase.

Now, we've pointed out "sufficient to be useful for inhibiting."

Now, Dr. Storer did introduce, by the latter part, did introduce testimony that is substantively the same thing.

And certainly Dr. Meier did testify regarding the inventors were in possession of a definite class. He went through the patent, formulas, illustrations, data, and so forth, and concluded that it was not limited to the specific options that are described at the 2' down position which was the issue we were looking at. So the issue had been decided.

There is no failure of proof on our part. We did not bear the burden of proof on this, but we came forward with lots of evidence once the jury could reasonably have concluded that they failed to prove this written description defense by clear and convincing evidence, as they were required to do.

It's an intensely factual issue like enablement.

And Dr. Meier came through with his testimony. He specifically was asked, after having reviewed all of those things, it was not conclusory. He went through the

patent in detail.

And he said -- was asked: Would a skilled artisan being able to recognize the 2'-methyl up ribonucleoside class of compound without having every member specifically listed?

And the answer was: Yes. Definitely.

It's a fact issue for the jury to decide. The jury would have credited that testimony as well as all the other evidence that we submitted on this and come out in favor of Gilead -- I'm sorry, come out in favor of Idenix. There is no matter of law circumstance here.

Your Honor, enablement is in the law to ensure that the public has adequate teaching commensurate with the right to exclude. And Gilead's counsel referred to the public policy behind this here, and he alluded to that there was a detraction, detraction from the field that may have occurred because of this patent.

And, Your Honor, we see anything but that here. We see that 11 out of the 12 compounds that have made it into clinical trials to treat HCV are compounds according to this patent.

The public got the teaching that they were entitled to in this patent. There is no better testament to that than the Pharmasset scientists who cited this paper for the proposition of a 2'-methyl class of ribonucleosides is

effective to treat HCV.

Without the teaching of this patent, there is no -- without that. I mean, they got 2' methyl idea from Idenix. That's where it came from.

So this patent provided the information necessary for Pharmasset to get its drug to market as well as for the good many other compounds that made it into clinical trials with a 2' methyl ribonucleoside structure as described in the claim.

We submit that there is ample evidence here under which the jury could reasonably have reached its conclusion that Gilead did not prove that the claims in this patent are not enabled or that they fail under the written description test.

THE COURT: Okay.

MR. GRIFFITH: Thank you, Your Honor.

THE COURT: Thank you very much.

Do you want rebuttal?

MR. SINGER: Do you want to take a lunch break?

THE COURT: No. I would rather hear from you first.

MR. SINGER: Okay. Your Honor, I guess I want to start -- I've got a lot and I will try to organize them as best I can.

I want to start really with something that

counsel for Idenix said in the middle that I found really remarkable, and just to remind the Court, that I think something to the effect of that Dr. Secrist sort of artificially inflated the numbers that are impacted here, and you wouldn't want to make a prodrug of an inactive compound. That's what's sofosbuvir was. The jury, no contest, no contested evidence about what sofosbuvir actually was. It was an inactive nucleoside, 6206, if the Court looks at record, that was then modified by Dr. Sofia to turn it into the great success that it is today, by adding a phosphate moiety to it to make it have some activity and then adding a prodrug. So the notion that someone wouldn't look at inactive nucleoside to then meet the effectiveness limitation is simply both remarkable given what was found to infringe here, what was conceived to infringe, but it's not supported by record.

Picking up on that, in terms of the sort of the numbers of compounds that are impacted by the claims, I heard an assertion that it was thousands. I don't think record has that number in it. Dr. Meier I believe said varied a lot of compounds if you look at what he said, and I will give you the cite, Your Honor. What he was describing was actually not a -- he was describing a theoretical approach tied to what was actually listed in the patent, not a theoretical approach divorced from the patent. You know,

counsel showed Dr. Secrist being crossed about plutonium and mercury. Well, plutonium and mercury, they're not listed in the patent as something someone of skill in the art would consider, ever. I think Dr. Secrist was saying the obvious, one can put plutonium on here.

But what Dr. Meier said, and this is at page 1918, is -- he's being asked that he disagrees that there are billions, and he says, you know, why is that number much too large? This is the -- of course, if you take the theoretical approach to discuss all the structures that are mentioned in the '597 patent, also in the '585 patent, then, and that's the priority application, then there are very, a lot of compounds. So he's talking about what is disclosed, that if you take those, there are a lot. And then he circumscribes it by talking about the 2' methyl and the inhibition of the NS5B polymerase. So it's either a lot or billions, but it's tied to the substitution that the patent recommends.

You asked, Your Honor, about this issue of making new compounds versus, you know, going to the library, if you will. Actually, Dr. Secrist was cross-examined by counsel on that very point, so the record does reflect, and I will direct your attention to page 1728 of Dr. Secrist's cross-examination.

"Question: And, by the way, sometimes you

wouldn't even necessarily have to synthesize it anew. Right? Sometimes you can find compounds in an existing library with it already available. Right?

"Answer: In an existing library, you mean buy it from somebody?

"Question: Buy it from somebody, or maybe if you are a large company, you have it in your library of compounds?

"Answer: Any company that worked on nucleosides would presumably have some. They don't last forever, but they would, and they're all different. But it is a pretty small number, very small number, I would say."

That's a record about what was available pre-existing that you didn't have to make. And it's ironic that Merck, the Merck library was mentioned, because the jury saw evidence about what Merck's views were on modifying nucleosides, and this is from, Your Honor, DX-2802, page 8, which is an e-mail that the jury saw about the Merck Isis collaboration, about the effort required. Along those lines I think we have to be very careful and clear about what we collectively chose to synthesize, since it is apparent that there may be a lot of synthetic effort required even for minor modification of compounds you already made.

So even suggesting, even stating that the methods were known to make nucleosides, the record before

the jury was not simply that it would be, snap, you just go to the library and, snap, you can make them, it took time. That's why Dr. Tausek talked about it would be a lot to do 37 a month, and Dr. Secrist said uncontested, that a person could make about two to four per month. That's what he talked about. Dr. Meier never addressed how much time it took.

The other point, Your Honor, is, in going through, if you will, the *Wands* factors, actually the record we presented on JMOL basically accepts what Idenix is saying with respect to how the jury might have found those. With respect to the scope of the claimed invention, I actually think the parties aren't in that big of a disagreement. There are a lot of compounds impacted by the structure that are then narrowed by the effectiveness limitation. That's the seventh factor.

And on operability, Your Honor, this is really a fact-based case on that point. Sure, there's some case law that talks about inoperative embodiments, but this patent as it relates to full scope has to enable the full scope, everything, because there are no inoperative embodiments by the nature of the claim language. The claim language requires that they be effective, that the 2' methyl ribonucleoside must be effective to treat HCV. So there are no inoperative embodiments possible by the claim. And all

the strikeouts that counsel is saying is permitted, that's the problem. Finding the effective ones, you strike out a lot. That's what the experts said. You don't know until you make a test, and that was record evidence before the jury about the struggles of Idenix to identify effective 2' methyl compounds.

And a couple more points, Your Honor. Again, I'm happy to address whatever the Court would like.

On predictability, Dr. Meier was clear that he was of the same view, that this was an unpredictable art, the art being the use of modified nucleoside to treat HCV. That was the field we had in this case. It's not the use of nucleosides to treat viruses, it's the use of nucleosides to treat HCV.

And I asked him, because if the Court will recall, Dr. Meier actually didn't even start working in the field until 2012. And I asked him on cross-examination about what he learned when he did this in 2012. Well, I was talking about 2012, and this is page 1929. When you started working on it, the "it" being the field of nucleosides for treatment of HCV, you learned how unpredictable it could be, didn't you? Yes, of course.

The other couple points, Your Honor, there was raised some case law and there was a heavy reliance on the *Wands* case, and that's an instruction that faces the Court.

It's the seminal case with the *Wands* factors. I actually think that's not correct, the 44 percent. That was sort of the inventive process that they went through. But the Court then commented on the actual practice of the claims. You know, if you practice the claims, would you always, or would you sometimes achieve inoperative results? And what the Court said at page 858 F2d. 740 is, you know, the Court is talking about that the antibodies used to practice the claim method are obtained by a process which entails, quote, "immunizing animals, using lymphocytes from the immunized animals with myeloma cells to make hybridomas and screening the antibodies produced by the hybridomas for the produced characteristic."

***Wands* carried out the entire procedure three times and was successful each time in making at least one antibody that satisfied all the claim limitations. Here, the evidence is that people would make things trying to satisfy the claim limitation and they would fail. And the only examples in the patent are with the one substituent bound do not go to the breadth of the possible substituents.**

Just one comment on *Wyeth*. I don't know if counsel misspoke or not, but the structure in *Wyeth* comparable to 2' methyl absolutely was identified. It was the macrocyclic structure. That was the discovery, that that macrocyclic ring bound in a certain way to achieve the

anti-restenosis effects.

And, Your Honor, an awful lot is being put on that grant application, and if the Court reads what was highlighted in slide, I think it's slide number 21, you will see it says, several classes of sugar modified nucleosides were recently disclosed. And, of course, the ribonucleoside, the sugar in its natural state, has 2' OH down and 3' OH down. And they can be divided. So that's what we're talking about, modifying the sugar of the natural ribonucleoside, which has the 2' OH and 3' OH. And then it goes on to say, they can be divided into the following three classes, and they highlighted the 2' modification of methyl, where 2' methyl is the modification, and then they identify the compound. Among them, 2'-C methylcytidine is representative of that class of modified nucleosides with a potent anti-HCV activity.

2'-C methylcytidine is methyl up, OH down, so all they're talking about is one of the very examples that's in the patent in suit. It's no more comment on the full scope of this claim as we transfer from OH down to anything else down at 2' than the patent does, which doesn't have any examples of that at all.

Your Honor, just a couple more points and then I will be done.

With respect to the Storer testimony, I think I

was making the point that there's a legal requirement in enablement to link the understanding of a person of skill in the art about this mimicry point to the disclosure of the patent, and this is the novel aspect of the patents-in-suit. It needs to be in there. You can't fill it with the testimony of a scientist talking about something else to, if you will, gap fill for enablement. That has to be in the patent specification. But I suppose even if there's some exception to that, that has to be linked, that a person of skill in the art would make that same conclusion after reading the patent specification. That would be sufficient to support enablement.

And then, Your Honor, with respect to Mr. Clark, again, I would just emphasize, you asked me, you know, isn't the jury entitled to accept certain things he said and object to other things he said? That's certainly true. But they're asking for an inference is what they are asking for, to infer that Mr. Clark was guided by the '597 patent. He testified that he went into the office with it, and they are asking that there be an inference given that you have to look at all the testimony and determine whether or not it was a reasonable inference.

And, you know, finally, Your Honor, subject to checking with these folks over there if I've missed anything, again, happy to answer any questions.

I just want to say, what we heard at the end was a plea, if you will, that this was an important and groundbreaking discovery, and the Court can very well find that. You know, I'm not here to talk about the merits. I think I said that at the beginning, that regardless of what the merits of the patentee might have contributed, the question for this Court is whether the claims of the patent go too far? Are they too broad given what the patentee actually discovered? And it's right there in the Ariad cases and all of them. Patents are not awarded for academic theories. And here I will say it wasn't just an academic theory, but the theory that any 2' methyl up would be active, that is an academic theory that is not borne out by the evidence, and no matter how groundbreaking or necessary to the later patentable inventions. That's from the ***Ariad v Eli Lilly*** case, Your Honor, 598 F 3d. 1353.

The fact that other molecules utilize 2' methyl, that's the point. They had to do the work to, if you will, later enable the full scope of these claims. They are not enabled by the patent specification, as I think the record amply demonstrates before this jury.

THE COURT: All right.

MR. SINGER: Let me just check if I missed anything.

THE COURT: I also have a few other questions

for you.

MR. SINGER: Okay.

THE COURT: Then I will let you check.

MR. SINGER: Very well.

THE COURT: On the *Wands* factors, is it your view that there's not a single change due to material fact with respect to any of the *Wands* factors?

MR. SINGER: I think there might be -- you know, I don't think -- no I guess would be my answer because we believe as a matter of law enablement, lack of enablement has been shown. I think there have been arguments made about the quantity of experimentation that is necessary that do not reflect what record actually shows, and about the scope of the structure impacted by the claims that are also not supported by what record shows, but in our view, the undisputed facts show a lack of enablement under the *Wands* factors.

THE COURT: There was some reference during Mr. Griffith's argument to the identification of a polymerase that was being attacked essentially in order to treat HCV. Is that an element of the claim here?

MR. SINGER: It is not an element of the claim. I mean, I think what I said at the beginning was that we dispute that that is an element of the claim. I don't think the Court needs to resolve that issue to decide Gilead's

motion here, but --

THE COURT: Does it have any relevance to the enablement question?

MR. SINGER: I think it does, Your Honor, in that the Court could readily find that the patent actually doesn't teach explicitly that the things covered by the claim have to be active with the polymerase. The patent actually says they may be active in the polymerase, but they also may act in other mechanisms, and the jury heard testimony about ribonucleosides, which is a nucleoside that acts through a different mechanism.

But I actually think in terms of resolving the issue, it's -- I don't believe it's necessary for the Court to resolve that issue to rule on the JMOL, because even accepting Dr. Meier's premise that the patent directs you to the NS5B polymerase, it still requires undue experimentation.

THE COURT: And on whether or not the patent teaches away from fluorine because it doesn't expressly disclose it, given the jury finding, could I in any way credit your argument about it essentially teaching away from fluorine?

MR. SINGER: I think, Your Honor, the jury is allowed to make those findings that are supported by the evidence. And I think you could find that the failure to

list fluoro, while listing it in other places, that the jury's conclusion that that is okay is not supported by substantial evidence. I don't see that the jury verdict is an obstacle to that finding.

THE COURT: Do you want to confer, see if you have anything else to add?

(Pause while counsel conferred.)

MR. SINGER: Your Honor, they are telling me I did okay.

THE COURT: All right.

MR. SINGER: We can go to lunch.

THE COURT: If you would like to add anything, you certainly may.

MR. GRIFFITH: Thank you.

First, Your Honor, on the point about Dr. Storer's testimony about mimicking OH, that goes in part to predictability, so this is, as I said, a tool that a skilled artisan used, and used at the time to synthesize, and so that was -- it was a predictive tool for them.

And the second point I would make about that is, and I apologize if I was less than clear in my first go round, is that that section of the patent that is talking about acting on the HCV polymerase and preferred embodiments specifically doing the HCV polymerase assay, that is honing in on the mimicry aspect of the invention.

So Dr. Sommadossi testified about this invention, that what happens is, you have to phosphorylate so that the ribonucleoside will be taken up by the polymerase, and then what happens is you have chain termination when it does. This is the way the HIV drug AZT worked, so that was his background in getting to this. AZT was a deoxyribonucleoside, but the concept was the same.

So the concept of mimicking the ribonucleoside is present in that disclosure in the specification talking about acting on the HCV polymerase.

And then the point I want to make about *Wands*, it was, the *Wands* -- Wands was the patent applicant in that case, and Wands himself argued that his success rate was four out of nine. That was the 44 percent.

And I was looking for the places in the specification -- in the opinion that noted that it was specifically called out in Judge Newman's dissent in that case, and I didn't see where it was specifically called out in the majority opinion, but it was Wands's position that he was successful 44 percent of the time.

And then elsewhere in the decision, page 738, *Wands* submitted a declaration first for fusions were unsuccessful and produced no hybridomas, the next six all produced hybridomas, hybridomas that may have antibodies specific for hepatitis B. Wands had failure. He had

failure.

Now, Mr. Singer pointed out that there was another instance pointed out here where screening antibodies all three times in the entire procedure, he got at least one antibody, but he had a lot of strikeouts.

And then in terms of why does that matter here is that we say that skilled artisans may experience some amount of, I've got a ribonucleoside that is not active, but that is not -- no evidence indicates that is happening with an undue occurrence rate or a substantial portion of the time.

And the second point on that is, so Mr. Singer pointed to, by definition, you can't have inoperative embodiments because this claim requires effectiveness.

I think the claim in *Wands* required the ability to bind the hybridoma at a certain affinity level. So it was the same situation, and it was the same issue, and that is do you have enough information to make compounds that are effective, that bind the HBV surface antigen that are effective against HCV? Do you have enough information in the patent for skilled artisans to practice the invention without undue experimentation?

The Court in *Wands* said yes. Even though more than half the time you are going to strike out, that is still not undue experimentation. And these experiments were a significant amount of time, working with animals, to do

fusions, to injecting animals, to develop the hybridomas.

So those the main thoughts that I wanted to go back to.

This is not a plea, Your Honor. This is simply a fact that in a motion for a judgment as a matter of law, Your Honor, it is a heavy burden to take away from what the jury did.

And there was a substantial amount of evidence submitted to this jury, including conflicting evidence. There is some waffling on whether there was conflict between the experts on does the target matter? There absolutely was conflict on that.

And it does matter because it is informative. It doesn't matter that it is not a claim element per se. It is useful and important information to the person of skill in the art that it can help guide them. And, indeed, indeed, that was information that guided Dr. Sommadossi and Dr. LaColla to this invention in the first place.

Thank you, Your Honor.

THE COURT: Thank you. Mr. Singer, any last word on this?

MR. SINGER: No, Your Honor.

THE COURT: All right. Well, we will take a lunch break. I recognize we're running more behind schedule. The arguments have been very helpful to this

point. I had indicated we would take an hour for lunch. If you want to come back sooner than that, that's fine by me.

Any thoughts by the Idenix side on how long you want to be given?

MS. PARKER: We think maybe 45 minutes for us.

THE COURT: Okay. Any problems with 45 minutes on the defendants' side?

MR. SCHERKENBACH: That's fine, Your Honor.

THE COURT: Then whatever 45 minutes is from now, we'll look for you. We will be in recess.

(Lunch recess taken.)

* * *

2:30 P.M. - Afternoon Session

THE COURT: Have a seat.

I hope you all had some lunch. I think we're ready to move on. Is there anything to add?

All right. Let's move on to the next issue, please.

MR. WARDEN: Good afternoon, Your Honor. Joseph Warden on behalf of Gilead. I will be addressing Gilead's JMOL on damages.

May I approach with some slides, Your Honor?

THE COURT: Yes.

(Slides passed forward.)

MR. WARDEN: Before I get into the specifics of

my argument, Your Honor, I want to start with one high level point.

Idenix in this case obtained a $2 and-a-half billion damages award which is the largest patent damages award in U.S. history and, in support of that award, was given the testimony of Mr. Andrew Carter, Idenix's damages expert.

And Mr. Carter here on this slide acknowledges that Idenix did not invent the cure for HCV. That cure came from Gilead's work.

Even assuming Idenix's patent is valid, it contributed one piece, methyl up. And methyl up, by itself, doesn't cure HCV. And for purposes of damages, methyl up does not bring any commercial success.

Now, we heard from Mr. Griffith talk about the important of methyl up and how 11 of 12 compounds that have gone through clinical trials are methyl up compounds, but what Mr. Griffith didn't say is only one of those compounds has ever been successful, sofosbuvir, as a result of Pharmasset and Gilead's work and in particular, the contribution of fluoro down and the prodrug.

And the other striking thing we heard this morning on that point is the admission first from Dr. Sommadossi that the '597 patent does not disclose fluoro down, and Mr. Griffith agreed with that and essentially

argued it doesn't, it doesn't matter. They don't have to disclose fluoro down.

And while Mr. Singer explained all the reasons why we disagree, even assuming that is true for purposes of validity, the question for damages is different, and that is what is the value of this patent? In particular, what is the value of a patent that does not disclose the only embodiment that has ever had any commercial success?

And with that, Your Honor, I want to get into the specifics of what went wrong with Idenix's damages presentation.

And at a high level, there were two problems:

The first of which is that Mr. Carter failed to perform the required license comparability analysis.

And the second I'll get to later is that he failed to perform the required apportionment analysis.

And just to reorient the Court:

Mr. Carter's entire damages case was premised on comparison to two past licenses: one between Merck and Roche and one between the Pharmasset and Roche, and using those two licenses is where he pulled his 10 percent rate from.

The Federal Circuit has explained that if you are going to do that, you have to account for the differences between your past licenses and your hypothetical

license. And Mr. Carter failed to do that in a number of important respects.

And I'm not actually going to take the time today to go through every one of these four. They're all talked about in our briefs, and we still stand by all of them. I want to focus on the first and the last because those are the most important here: the impact of portfolio licenses or the number of patents and the impact of the nonpatent assets that were licensed.

First is the differences in the number of licensed patents.

Here, Your Honor, are excerpts from both the patents or, excuse me, both of the licenses that Mr. Carter relied on showing that both of them gave Roche license or rights to an entire portfolio of patents, not a single patent.

And the Federal Circuit in, and this Court, have both explained that portfolio licenses are not comparable to single patent licenses.

In *Lucent*, the Federal Circuit, said, A reasonable juror could only conclude that they were vastly different.

In *AVM Technologies*, Judge Andrews said, A patentee cannot even argue they are comparable.

And that doesn't, Your Honor, mean that a plaintiff can't ever rely on a portfolio license. Judge

Andrews, in another case, *Inventio*, explains how and when you can use a portfolio license as part of a comparability analysis.

In *Inventio*, Judge Andrews allowed the use of that license, the portfolio license only because the expert took into account the need to make a significant downward adjustment to the royalty rate. The expert didn't just extract a rate from the portfolio license. If Mr. Carter wanted to use portfolio licenses, that is what he was required to do.

Let's look at what he actually did do.

Mr. Carter testified that the number of patents didn't matter. That it didn't affect his rate.

That is problematic for a number of reasons. The main one being it contradicts the law in *Lucent*, in *AVM Technologies*, and in *Inventio* which say, no, portfolio licenses and single patent licenses are very different and you can't compare the one to the other without making a significant downward adjustment.

And, Your Honor, this case actually provides a really good example of why portfolio licenses and single patent licenses are so different and can't be treated as though they're the same.

Roche, in its two licenses, got the right not just with a single patent but protection from the future of

any other patents being asserted against them. So Roche would never have to face the situation where Merck came back a year later and said, hey, we've got another patent we think covers your product. Now you need to take a license to that one and wouldn't have to serially defend it from patents from Merck or Merck's affiliates.

Gilead didn't get that. Gilead is getting a license to one patent. And if Gilead were getting what Roche got, Gilead wouldn't find itself in the situation of having to serially defend itself against the patents of Idenix and its affiliates. It wouldn't be defending this case in this court. It wouldn't be defending against Merck's patents in California. It wouldn't be in front of the Federal Circuit still fighting about the '600 patent. And it wouldn't have to worry that a year from now, Idenix might identify another patent that it thinks the covers sofosbuvir and assert that against Gilead.

Simply put, Mr. Carter is charging Gilead the price for a portfolio license but Gilead is not getting portfolio protections. The case law says that is not a comparison Mr. Carter was even allowed to make.

THE COURT: Are you saying that an expert cannot opine that the number of patents being licensed does not matter?

MR. WARDEN: I am saying that under the case

we cited, he can't say it doesn't matter. There might in theory be a situation where he might offer an explanation for why a single patent license could have the same rate as a multiple patent license under some circumstances, but he has to address it. He has to talk about the difference.

And he said I can disregard the difference. He says the number of patents doesn't make a difference in the rate. That is not allowed.

What he needs to do, as *Inventio* says, is to, well, in that case at least, make a significant downward adjustment to the royalty rate but critically to account for the vastly different bundle of rights conferred and not simply extract a rate from the portfolio license.

THE COURT: Are you saying the law requires an expert to opine that the value of a license to a smaller number of patents is per se less valuable than to a portfolio or a license to a larger number of patents?

MR. WARDEN: I think the law does require an expert to opine that a value of a portfolio license is not the same as the value of a single license. I think *AVM Technologies* says that extremely clearly:

"A patentee may not argue that prior licenses granting rights to entire portfolios of patents are comparable to a license that the parties would have negotiated for a single asserted patent."

I think that is a clear statement of law, also consistent with what the Federal Circuit said in Lucent. That error, by itself, renders Mr. Carter's damages analysis legally unsupportable.

There are several other problems with Mr. Carter's license comparability analysis. And in the interest of time, Your Honor, I'm not going to go through all of them.

The next one, the difference in timing and risk as well as technological comparability. We have covered these in our brief. We stand by what we said in our briefs.

But I want to again focus on the other part of the comparability analysis that I think is the biggest problem here, and that is Mr. Carter's failure to account for nonpatent assets. And this relates really to the Pharmasset/Roche agreement.

And the first thing I highlight, Your Honor, is this Pharmasset/Roche agreement is not a license agreement. It is entitled a Collaboration Agreement. The reason it is entitled a Collaboration Agreement because it covered a lot of things and an patent license was only one of many parts.

And, critically, one of the things that it covered was the actual PSI 6130 compound. Pharmasset didn't just give Roche patent rights, Pharmasset gave Roche PSI 6130, gave them an exclusive license to develop PSI 6130.

They gave them samples. They told them how to make it. They gave them anything that was necessary or useful for the manufacture, development, or commercialization of it.

They gave Roche everything that the '517 patent doesn't give: actual directions on how to make this compound, the actual physical compound.

And here is what Mr. Carter had to say about that -- six words.

In talking about that patent or that license, he mentions in passing it was for the 6130 drug and the related patents. And then he never talks about this point again. He never tells the jury how that impacts his analysis. He never adjusts the rate for that license to account for the fact Pharmasset wasn't just getting a patent but was given the key compound they were working on. That never affects his analysis.

And under far less egregious circumstances, the Federal Circuit has set aside damages award. In ResQNet, the Federal Circuit set aside a damages award that was based on licenses that included non-patents, like "finished products, training, maintenance, and marketing."

And in Trell, which was relied on by the Court in ResQNet, the Federal Circuit set aside a damages award that was based on a patent or on a license that actually covered the patent-in-suit but also conveyed other rights

that were more broad than just the patent-in-suit. And the Federal Circuit said you can't just pluck a rate out of that license when it covers more than just the patent-in-suit. And it set aside the damages verdict.

Those two comparability points I think are the most egregious, Your Honor. I'm happy to address the other comparability issues if the Court has questions before I move on to the apportionment issue.

THE COURT: The only question is when you suggest that Carter failed to address things, what I'm hearing you say is that while he referenced them, while he was made aware of them, perhaps even on your own cross-examination, you don't like the answers he gave and you think that they are inadequate in some instances under the law. You don't mean to say he was, as far as the jury was concerned, ignorant of factors that you are pointing to, do you?

MR. WARDEN: I don't mean Mr. Carter was ignorant. What I mean is that Mr. Carter I think intentionally disregarded factors that as a matter of law he was required to take into account and make adjustments for.

THE COURT: But by disregard, do you mean there is nothing in the record where Mr. Carter says anything about these factors?

MR. WARDEN: So with respect to the 6130, the

fact that the Pharmasset and Roche agreement included 6130, he says right here, it was for the 6130 drug.

THE COURT: And the related patents.

MR. WARDEN: And related patents, but then he is focusing on the fact it is a patent license. He never talks to the jury at all about how the fact that it also covered this drug impacted the rate in that Pharmasset/Roche license, and he never adjusts the rate downwards in his hypothetical license to account for the fact that Gilead was not getting a complete finished compound from Idenix the way that Roche was getting it from Pharmasset.

That is something that he was not allowed to do. The Federal Circuit had said that. You can't just take a rate from a license that gives patent rights and a whole bunch of other stuff and then use that same rate in your hypothetical license that only gives patent rights. That is exactly what Mr. Carter has done here. As a matter of law, he was not allowed to do that.

THE COURT: Okay. You can move on if you wish.

MR. WARDEN: So the second issue is Mr. Carter's failure to satisfy the apportionment requirement.

This is the same slide that I showed at the beginning, Your Honor, that Mr. Carter is acknowledging Idenix is only contributing a piece of sofosbuvir, that is the methyl up, whereas Gilead is contributing the other two,

or at least two other pieces, fluoro down and the prodrug.

Here, Idenix's counsel in opening statement acknowledged the same thing. And this is just a graphic sort of showing that how you can divide it up into at least three key pieces, only one of which was the contribution of Idenix's patent.

And there is a fair amount of briefing, Your Honor, on the question of whether under these circumstances the Entire Market Value Rule comes into play. We stand on that point by what we said in our briefing. We think it does. We think Idenix is required to satisfy it.

I'm not actually going to talk about that now because ultimately it doesn't really matter, and the reason it doesn't matter is because in *AstraZeneca*, the Federal Circuit explained that even if the Entire Market Value Rule doesn't apply, there is still a related inquiry that has to be done which is substantially same kind of analysis.

What *AstraZeneca* said is where you have a drug that covers, or a patent that covers a product, a drug as a whole, but where the patentee only invented one element of what is claimed and the other elements were not invented by the patentee, you actually have to do an apportionment, where you compare the value of the element that the patentee invented to the value of the elements it didn't invent. And I prepared some graphics to show how this played out in

AstraZeneca. In ***AstraZeneca***, the drug was omeprazole. It had three elements, a core, a subcoating and enteric coating. What ***AstraZeneca***'s invention was, that that combination, they didn't invent the actual individual elements, but they figured out if you arrange these elements in this particular way, it has benefits. They invented the recipe, not the ingredients.

And what ***AstraZeneca*** said is, well, what we have to do is we have to compare the value of ***AstraZeneca***'s invention, which is the combination, to the value of the other elements that they didn't invent standing alone. And in that case, the Court concluded, well, here, ***AstraZeneca***'s contribution, the recipe is actually what drives the value for this product, and so the Court allowed use of an unapportioned royalty base.

That same analysis needs to be done with respect to sofosbuvir. Sofosbuvir has at least three elements, methyl up, fluoro down and a prodrug. Idenix invented only one of those elements, the methyl up piece, and under ***AstraZeneca***'s analysis, the other pieces, fluoro down and the prodrug, are other elements.

Under ***AstraZeneca***'s analysis, Mr. Carter was required to do an apportionment analysis between the value of Idenix's invention, methyl up, and the value of the other elements that Idenix didn't invent, including fluoro down

and the prodrug. He didn't do it. And I just want to make clear in case we hear from Idenix that, you know, he did do it somehow in his apportionment of the royalty rate, which is not true, but, more importantly, as a matter of law, it has to be done on the royalty base. Both *Laser Dynamics* and *Uniloc* talk about the fact how this kind of apportionment has to be done on a base, not a rate, because the use of an unapportioned royalty base can unfairly skew the damages award high when the jury sees it.

So Mr. Carter was required to apportion the base. He didn't. This is a second independent reason why Mr. Carter's damages analysis is insufficient, and why there is no legally sufficient evidentiary basis for Idenix's damages award.

The last point I conclude on, Your Honor, is the remedy, so to speak. We've asked the Court to grant judgment as a matter of law as well as a remittitur. In this case, while Idenix did not present a legally sufficient evidentiary basis for its damages award, there was a sufficient evidentiary basis put in by Dr. Putnam for damages of no more than $380 million, and what this Court and the Federal Circuit have explained is that where there's no support for a jury's award, this Court can remit it down to the maximum amount that is supported by the evidence. In this case, that's $380 million, and that's what we would

ask the Court to order as the appropriate damages in this case.

THE COURT: If I do think that there was a legally admissible basis for Dr. Carter's analysis, is there any other basis on which you are entitled to relief with respect to damages?

MR. WARDEN: The only thing we've moved on is Mr. Carter's analysis, which was the entire basis for Idenix's damages award.

THE COURT: Okay. Thank you.

Ms. Swize?

MS. SWIZE: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MS. SWIZE: May it please the Court, I do have some slides that I'm not going to go through in its entirety, but if I may hand them up?

THE COURT: You may, sure.

(Ms. Swize handed slides to the Court.)

MS. SWIZE: Your Honor, a jury had substantial evidence to adopt Mr. Carter's royalty analysis, which it adopted in its entirety, and I'm just going to jump right into the complaints that Gilead has raised, starting with its license comparability challenge.

I'm going to go by very quickly the basis of Mr. Carter's analysis, which was a license comparability

analysis. He analyzed the parties. He compared them to Idenix and Gilead and he looked at the royalty rates. He also supplemented his opinion with Georgia-Pacific factors. He did address Gilead's complaint, which I will get to, and he opined on the ten percent on net sales.

So let's go to the first of Gilead's challenges on the number of patents that were covered in the comparable licenses.

So the first point is that these are issues that the jury could weigh. The Federal Circuit has been very clear that on the complaints that Gilead is raising, those are issues about weight for the jury to decide, the degree of comparability, and whether and how the expert has controlled for different variables, because obviously we're talking about not an apples-to-apples comparison, but an apples-to-oranges comparability. The Federal Circuit does not require identity.

Then we go to the first point on the number of patents in the licenses. This goes to weight. It was the jury's decision to decide how much weight to give this. I heard a suggestion, this was maybe something in theory where an expert could rely on a license with a different number of patents than the patents in the hypothetical negotiations. We don't have just something theoretical here. We have a reasoned analysis, because this issue was presented to the

jury.

And Mr. Carter didn't just disregard it because he ignored it. He said, the parties' comparable licenses do disregard the number of patents. They have the same royalty rate regardless of the number of patents that issued or expire, come in or out. So he acknowledged it and said it wouldn't matter in this kind of negotiation in this industry where Idenix and Gilead would be coming to the table as well.

On the other assets, this was also presented to the jury. Mr. Warden suggested that it wasn't, and he said in his testimony or his presentation that Mr. Carter said about six words on this. That's not true. That's not accurate. Mr. Carter was cross-examined extensively by Gilead. It was exactly what the Federal Circuit said in Active Video. That's the best way to assess comparability, have the expert examined on it and cross-examined on it. And Gilead's counsel I don't think mentioned the other license that Mr. Carter relied on, which is the Merck-Roche license. And on there, in terms of the other assets that were covered by other agreements in that package, there was evidence in the record, and Dr. Putnam, Gilead's expert, was asked about this, where the rates would have been higher if those other assets had not been included. In other words, those were accounted for, and for both of the licenses that

Mr. Carter used, they used a range, but Mr. Carter did adjust, and he adopted at the low end of both of those accounting differences.

I will turn to Gilead's argument on the royalty base and whether it was appropriate to use sofosbuvir. It was. Your Honor may remember, this was an issue that was before the Court on the *Daubert* motion that Gilead brought, and Your Honor said that our expert, with respect to damages and the entire market value rule, gives a reasonable, reliable opinion, and that the patented feature may not under the circumstances be segregated out, and the patented feature may be found to drive demand, a reasonable valuation. The jury doesn't have to agree. They could challenge it and the jury could accept it, and they did accept it here.

And I have five points on this, and I will be brief.

First, with respect to *AstraZeneca*, I think that answers our case entirely, because while the Federal Circuit did not say it's a per se rule in the pharmaceutical context, there is something about this context that really does not fit. You can't really divide it up like electronic components where this rule usually arises.

And with respect to our case, we are like *AstraZeneca*. Our claims do not cover methyl up. That's not

our invention. Our invention are ribonucleoside, a class of ribonucleosides that include a prodrug at the '5 position, the fluoro at the 2' down position. That's all part of our claim so we're exactly like *AstraZeneca* in that respect. But in our case we have even more than *AstraZeneca*. We have the record in this case, where the entire trial the jury heard about the entire molecule being an appropriate base. The two licenses that Mr. Carter used did the same thing. And we did not have any dispute from Gilead's expert. There was no offer by Dr. Putnam to divide sofosbuvir up the way the diagram presented today did because somehow it separated out. Dr. Putnam did not dispute this. He offered no alternative view. In fact, he essentially endorsed it when he converted one of the licenses into a lump sum using net sales of the royalty base.

And my final point here is that this really is different than the electronics context, which is where Gilead's cases arise. So in short, the jury was entitled to adopt our damages theory and award a reasonable royalty to compensate for the infringement of ten percent on net sales.

If the Court has no questions?

THE COURT: No. Thank you.

MS. SWIZE: Thank you.

MR. WARDEN: I will just touch on a few additional points, Your Honor.

First, I just want to make clear that we are not arguing that the licenses that Mr. Carter relied on were inadmissible. Counsel for Idenix made some suggestion that the issues we talked about go to weight and not admissibility and we're not disputing that. What we're saying is even if they were admissible, the Federal Circuit makes clear you can't just pluck the rate out of those licenses. You have to adjust that rate to account for differences. And that is where Mr. Carter failed, was to adjust the rate to account for differences.

So one of the things that counsel said is that he did give testimony about how licenses to single patents, it is appropriate to use the same rate of a license to portfolio. That's not actually what he said. Here's the testimony she's referring to, which I don't believe was shown during Idenix's presentation.

What Mr. Carter says is that when you've already got a rate in a license, once that rate has been agreed to, you don't adjust that rate every time a new patent expires or a new patent in the portfolio issues. That rate within the patent stays the same. We're not disputing that.

The question is: How do you set that rate in the first place? And is the rate the same for single patent licenses as for portfolios? And the Federal Circuit has clearly answered that question. A patentee can't

even argue that they're the same. That's what Judge Andrews said in *AVM Technologies*. In *Lucent*, the Federal Circuit said, a reasonable juror could only conclude that they're vastly different. And, again, Judge Andrews said, if you want to use them, this is how you do it. You can't just extract the rate out. You have to adjust it downwards. That's where Mr. Carter failed, was to make the necessary adjustments.

I want to just now go to the apportionment and *AstraZeneca* point. What I did not hear counsel for Idenix address was this other inquiry. We understand there's a disagreement between the parties about whether the EMVR comes into play in *AstraZeneca*, but we're setting that aside, maintain what we said in our papers about that. *AstraZeneca* still says that you have to do this related inquiry, and especially when the patent covers the infringing product as a whole. Idenix is arguing our patent covers sofosbuvir has a whole. Therefore, we don't have to apportion, except that's exactly when *AstraZeneca* says this related inquiry comes into play. And what you have to do is you have to examine the value of the elements that they contributed to that whole, in this case, that's methyl up, and you have to compare that to the value of the elements that they didn't contribute.

And we heard concession from Mr. Griffith this

morning that Idenix didn't contribute fluoro down. Dr. Sommadossi said the same thing. Under *AstraZeneca*'s related inquiry, they were required to do an apportionment analysis here.

And I want to point out what was said during the Daubert hearing on our motion for the entire market value. What the Court said was that it's possible that Mr. Carter at trial will be able to show that the patented features are the basis of customer demand. Maybe the jury won't accept it, but it's possible heal be able to show it and he's going to be allowed to go forward with that.

But Mr. Carter didn't even try to show that at trial. Instead, at trial, Mr. Carter changed tacts. He said, I don't even need to deal with apportionment. I'm using licenses instead. And he readily acknowledged that elements other than what Idenix invented contributed to the value and demand for sofosbuvir. He said, Idenix is bringing its patent to the table, but Gilead is bringing everything else. Gilead has to provide the drug that cures you. Gilead is the prodrug that gets the curative drug into the body. Mr. Carter did not try to show that the patented feature, methyl up, was the basis for customer demand.

I don't have any other issues that I want to address unless the Court has additional questions.

THE COURT: Yes. For damages purposes, I have

to assume that the patent is valid. Correct?

MR. WARDEN: Yes.

THE COURT: So I have to assume that the patent is enabled. Correct?

MR. WARDEN: Yes.

THE COURT: And so if it's enabled, their view is that it enabled the embodiment, including the accused ones, of course. Right?

MR. WARDEN: I'm not actually sure that is their view. What I heard Mr. Griffith saying during his argument is we don't need to enable the infringing product. I wrote that down verbatim. I think their view is they don't have to enable sofosbuvir. And more critically, even if it's enabled from a legal standpoint, the question on damages, is what is the value it contributes? How much of sofosbuvir does it get you? And there, no one is disputing it gets you one piece. It gets you methyl. That the work of getting fluoro, the work of getting the prodrug came from Mr. Clark and it came from Mr. Sofia, and Idenix doesn't get credit for that for purposes of damages, when we're trying to divide up how to give credit for the commercial success of sofosbuvir.

THE COURT: Okay. Anything else?

MR. WARDEN: Nothing else, Your Honor.

THE COURT: All right. What's next?

MS. PARKER: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MS. PARKER: If I may have just one moment, and I have a hand-up, if I may?

THE COURT: Sure.

(Ms. Parker handed slides to the Court.)

MS. PARKER: Your Honor, my motion that I'm going to argue is our motion for enhanced damages, and I know Your Honor is very familiar with the case law and the *Read* factors and all of that, so I'm going to focus more on the facts and circumstances here that support enhancement, and we start, of course of course, with the jury verdict.

As your Honor knows, the jury checked "yes" to that first question on the verdict form. There's more than just that. Under *Halo*, one of the primary factors is all of this bad conduct warranting enhanced damages, which is described specifically as characteristics of a pirate, and believe it or not, in this case, the testimony from one of the Pharmasset scientists actually used that word. His trial testimony that was played to the jury was that this was a piracy that would go on in Pharmasset at that point in time.

Your Honor is familiar with the *Read* factors. The biggest issue here in any case where there's an enhancement of damages is to look at the facts and

circumstances of the particular case. The one thing that Your Honor should respectfully consider is this pre-patent misconduct. That's an argument that they make in their brief. There are a number of cases, including *Read* itself, that says you need to look at the pre-patent conduct as well. And Your Honor has addressed this issue before trial when Your Honor allowed this testimony in.

So what was all of that? Well, let's start with Dr. Schinazi. Dr. Schinazi was an insider at Idenix. He admitted he had a large amount of confidential information from Idenix. He knew he was supposed to keep that information confidential within Idenix and not to be shared outside of that company. He had a position of trust. He had a duty of loyalty. He signed documents, including this, as one example, this confidentiality agreement here on the screen. He admitted in his sworn deposition testimony that was played to the jury that he had this confidential information that Idenix was developing compounds. He also testified at his deposition that he obtained the information about 2' methyl and its importance from Idenix. And he admitted that when he got that information, he knew it was not public knowledge. He knew that Idenix had filed a patent, and he knew that that information was covered by the patent.

THE COURT: Let me stop you there. The jury

found willfulness, as you pointed out. Let's assume for the sake of argument that I agree there's substantial evidence to support that. What if I subjectively don't believe that that is what happened? In making the enhancement decision, do I have to defer to the jury's finding or can I rely on my own views?

MS. PARKER: Your Honor, I would respectfully submit that Your Honor is bound by the jury finding of willfulness here.

Now --

THE COURT: Bound to believe that there was willfulness, but then the enhancement decision is discretionary.

MS. PARKER: Exactly. Exactly. It's just the first step. It's a big part of it. It's a big first step. But just because the jury found willfulness does not mean automatically enhancement. Enhancement is in your Honor's discretion based on a number of factors.

THE COURT: In enhancing my discretion, is there no role for the judge to have his or her own views based on reviewing the evidence?

MS. PARKER: Is your question, respectfully -- is your question only about the willfulness part or all of the factors?

THE COURT: Not the willfulness. We're really

focused on enhancement for the moment. I mean, another way to put it is, of course, the jury was entitled to make no credibility determination. We can infer what they were based on their verdict. What if I, having looked at the witnesses, had a different view of somebody's credibility? Can I consider that in making the discretionary enhancement decision or is that off the table?

MS. PARKER: Are you asking about a different view of credibility on the issue of willfulness or other issues that are relevant to enhancement?

THE COURT: Let's assume that it's an issue relevant to enhancement.

MS. PARKER: If it's an issue relevant to enhancement other than the willfulness, I think that's entirely within your Honor's discretion. I do respectfully believe that once the jury found willfulness, once the jury made that determination, I believe that does bind, so to speak, the Court as to that aspect of the entire analysis that goes into enhancement. And the jury found it. The jury has spoken, and the fact that the jury found willfulness is such an important factor in a number of these cases. The deference to the jury of, okay, the jury has already found willfulness is like the first major step.

I honestly don't think that I've seen any case where a Court has gone back and said, well, I'm not

going to accept that jury's finding. I think all the cases, to my memory, I think all the cases that I've looked at, and we've looked at a lot of them, accept the jury's finding as the first step and then go on and look at all the different, all the other facts and circumstances that are to be considered as far as the discretion in determining enhancement overall.

May I -- should I continue?

THE COURT: Sure.

MS. PARKER: Okay. So the next step is Dr. Schinazi gets this information that he learned from Idenix, and he admitted, and here's just an e-mail from him. He admitted that he violated his confidentiality agreement and provided that information to his own scientist. He breached his duty of loyalty. He breached that trust that he had with Idenix and gave that information to, to begin with, Dr. Watanabe. He admitted that. He said Dr. Watanabe must have turned around and given it to other scientists and that's how all of this started.

Dr. Schinazi also admitted in his deposition that he knew that this work that Dr. Hassan was doing, he specifically references Dr. Hassan, he knew those particular compounds belonged to Idenix.

And that is what led up to this e-mail that Dr. Stuyver, who was a top scientist at the time, sent to

Dr. Schinazi. This is the one, Your Honor will recall, from trial where he said I had to take a cold shower. He said when I found out about this, when I found out about this Idenix patent, I knew there was nothing left of the work we had done. He said we're just going to have to take a license. He says to Dr. Schinazi: What do you think about the fact that all this work we have been doing may eventually might end up belonging to Idenix?

Then, of course, we talked about several times today Jeremy Clark goes in and talks to Dr. Otto about the work he is doing and he takes the patent with him.

Again, knowledge that they knew about the patent.

And then that brings us to some of the internal meeting minutes that we obtained during discovery in the case.

There are a number of them, here is just one example, where they are talking internally about the work they're doing. This is not for any reason other than their own recordings of the work that the chemistry department is doing. And they say, over and over and over, they're working on Idenix.

Here is another example. All of this is in evidence, of course.

THE COURT: Right, it is. So I don't think you need to go over it again.

But here is another I guess way of asking the question. You had your spin on all of this evidence. They had their spin on it. It seems pretty clear which side the jury agreed with. But, again, if I don't buy that story, the one that the jury bought, are you saying for purposes of deciding whether to exercise my discretion to enhance damages, I have to buy the story?

MS. PARKER: No, Your Honor. Let me see if I can try this again.

What I'm saying is I think Your Honor cannot reject the jury's finding of willfulness. The jury has decided willfulness.

THE COURT: Okay.

MS. PARKER: But there is more.

THE COURT: That "at least" means I need to ask the enhancement question; right?

MS. PARKER: Right.

THE COURT: If I reject willfulness, then I don't even have to get there.

MS. PARKER: Exactly.

THE COURT: But does it mean more that I have to ask the question of enhancement?

MS. PARKER: Again, I believe it does. Because I have not -- it doesn't mean automatically that we get enhancement, though. It means, though, it is one factor

that I believe Your Honor must consider in looking at all of the facts and circumstances under *Read*.

And, again, I haven't seen a single case where a Judge has not accepted that finding of willfulness and not discussed that finding of willfulness in reviewing the *Read* factors.

THE COURT: So one factor that I want to understand your view of is the size of the damages verdict.

I think your position is it really doesn't matter, but is that how I should view it? That even though we're talking about very large numbers here and increasing them would by definition be very large, that is not a consideration that should get any weight in this case?

MS. PARKER: Your Honor, that is exactly what the law is. There is no aspect -- and actually Your Honor wrote this I think in the Power Integrations case. There is no aspect of punitive damages to the jury's award. The jury's award is entirely compensatory and no aspect of that -- it was not Your Honor's case, it was *Pall Corporation*.

The compensatory verdict is not to punish, it is entirely to make Idenix whole. So there has been no punishment at all of Gilead so far.

So it's kind of apples and oranges. What happened so far is an entirely different issue than what is before the Court in the motion for enhancement.

THE COURT: All right. So then when we talk about punishment, why is it not very relevant that here, the combined efforts, whether they were intentionally combined or not, led to a cure of a very serious disease here? Why should the Court want to punish that?

MS. PARKER: Your Honor, I think that has been addressed very well in the *Johns Hopkins* case in the District Court decision there. That was a case involving a cure treatment for leukemia which is again a very serious illness that can cause death in patients.

And, same situation, the defendant there said, well, this is a treatment that's used to help people and cure people and save lives. And the Court there had a very good couple of paragraphs saying, well, yes, we're not disputing that. You know, that is part of it. But you also have to take into account the rest of the situation. You have to take into account the bad conduct, the misconduct that happened along with it.

So there is no exception to the statute for treatment that is successful here. And I think that Johns Hopkins decision, which was from 1997 from this Court, I think it's instructive in terms of how Your Honor should consider that. It's just it's not, it doesn't cure the problem.

THE COURT: But you're not arguing that I

shouldn't be cognizant of the fact that end result of whatever the defendant did, good or bad, turned out to be a cure for a very serious disease?

MS. PARKER: I think that is one of the facts and circumstances of the case. And I think it is entirely appropriate for Your Honor to rely on it as well as others.

What I am saying, though, is that does not negate, that does not prevent enhancement when there are other factors that are in our favor for enhancement here.

THE COURT: So a key theme of the case that you argued was that they took your invention, essentially the 2'-methyl up, and they improved it. They made it better. They indisputably did things that you hadn't done to it.

If I accept that theme, how do I square that with now turning around and punishing them?

MS. PARKER: Well, that was factored into the damages here. That was factored into the compensatory damages. That was factored into the discussion about the damages that we just had with the motion that related to that. That was part of what the jury considered when the jury came back with an award. That is why we asked for 10 percent. We didn't ask for 100 percent.

You have to remember I think another factor that is very important for the Court to consider. Even after the compensatory damages award here, and even if Your Honor

were to treble the damages here, Gilead is still left with billions and billions and billions and billions of dollars from taking our ideas that were covered by this patent and wrongfully using them. So there is more to it than just, oh, well, they did something to help get this to the market.

THE COURT: Isn't the taking what you invented and looking at the application and the patent and citing the scientific articles and coming up with a way to improve it, as you yourself argued, isn't that exactly what the patent system is supposed to be encouraging the parties to do?

MS. PARKER: The patent system does not encourage anyone to use a position of trust that they have with the company to get inside confidential information, take it outside of the company in violation of their agreements and their duties to that company, turn around, wrongfully give it to their own scientists, for their own scientists to then copy and use and then cover it up.

That is a big part of this that we haven't talked about yet. They had a guilty mind. They knew what they were doing was wrong. That is why we had all those documents at trial where they said delete this data and avoid using the word "Idenix." Because they knew what they were doing was wrong.

That is misconduct. That is not the kind of corporate citizenship that this Court should sanction. That

is exactly the type of corporate misconduct that should be covered by this enhancement motion. That is something that this Court should not sanction. Instead, this Court should punish it, and the Court should award enhanced damages as a deterrent to Gilead and to other companies so that this won't ever happen again, so nobody else will go out there and do this.

THE COURT: One of the arguments I think you make in the papers is that there is no actual contemporaneous evidence of a subjective belief that they didn't infringe. I thought that there was some testimony at least from Dr. Otto to that effect when he and Mr. Clark were looking at the application or whatever it was at the time. Is that not evidence of a contemporaneous belief?

MS. PARKER: Your Honor, let me ...

If we could go to the slide right before that, I believe.

So, Your Honor, to answer that question, let me first start: So during discovery, we sent discovery asking if they had any witness, if there was any human being who had a good faith belief. And they did not identify Dr. Otto, they didn't identify anybody. And that is why Your Honor had that hearing last summer, and Your Honor granted our motion to strike the good faith -- their defense of good faith belief of noninfringement. So they didn't

even list him before trial.

At trial -- if you could go to the next slide, please -- the jury's finding here shows that they rejected that testimony. His testimony, Your Honor, I would respectfully submit is just not credible.

Remember he said I'm not even, I'm not even considering all of this about Dr. Schinazi, because Dr. Schinazi was not officially an employee of Pharmasset at the time. While all the other witnesses said he founded the company, it was his baby, he was telling them what to do, he was running the company.

But part of Dr. Otto's -- but Dr. Otto admitted he was not even considering any of that when he was giving the testimony about what he thought at the time.

And then also remember Jeremy Clark just flat contradicted what he said. Jeremy Clark said, Well, I'm the one working on it. I'm the one that is making this compound. I think back at that time, whether it was in somebody's patent or not was not my concern.

So the whole story that Dr. Otto told, first of all, it is not even identified before trial. Your Honor struck that. Then he comes in and says, well, here is my view, but it is not based on Dr. Schinazi at all and intentionally excluding that for that technical reason that maybe he is not an employee.

Jeremy Clark says that is not true. I'm the one doing it, and I didn't consider what was in the patent or not.

So I respectfully submit that his testimony just is insufficient to form a good faith belief.

THE COURT: It did come into evidence, though.

MS. PARKER: It is in evidence.

THE COURT: And I take it, this is an example of something you would say I think I can't find Dr. Otto credible.

MS. PARKER: Your Honor, I would -- that's correct. Your Honor, I would again say for all these different reasons that he wasn't even listed before. He said I'm excluding Schinazi. He said what he testified to is directly contrary to what Jeremy Clark said. I just don't think there is a basis for Your Honor to consider that to be credible within light of the jury's finding.

THE COURT: Another argument that was made, I think this one was made against your side, is that no one associated with Idenix ever even alleged that Gilead had basically stolen or acted like a pirate and taken your invention until this lawsuit, which was roughly 2013, I believe, even though Pharmasset had gotten a patent and done a presentation. Isn't that correct on this record?

MS. PARKER: Well, a couple of things.

One is before this lawsuit, we did not have any of this internal information, these internal documents that we now have. So, no, we did not have the same information back then that we have now.

But we did, as soon as we found out that there was actually an infringing product, we filed the lawsuit. Before then, there was no infringing product, so there was nothing to file a lawsuit about.

THE COURT: Right. Well, the story at trial was that back in I think 2001, it turns out they were stealing your property. You would have known about that by at least 2005 when they got their patent?

MS. PARKER: We didn't know the whole story. We didn't know the extent of it. That is the information. That additional part is what came out at trial, came out during discovery. So before the trial, no, we did not know that whole story.

Now, I would also like to mention that in looking at all the cases and all, I bet if you went back to all the cases that have been reported where there is enhancement, whether it is from the District Court level or on appeal, I bet you that there are -- you could go back and find out this information. I bet you there are a number of those as well where the plaintiff had information beforehand, and maybe not everything like here but didn't file a lawsuit before when the

infringing product came out.

That is just not a factor. That is just not relevant here. That just doesn't have anything to do with the situation.

When there were infringing products, when we knew they were going to hit the market, we filed a lawsuit. Before that, we didn't know this whole story. So I don't see how that -- I mean I understand, I think I understand Your Honor's question, but I don't see how that that can be a fact that would weigh in against enhancement.

THE COURT: Well, I think if I'm permitted to consider whether or not the real world facts are what you maybe persuaded the jury what you think they were, if I'm permitted to evaluate that for myself, if I weigh into my thinking that you would or should have known at least as early as 2005 that some of what you now say is what happened, all that bad stuff about Schinazi and others, that you would or should have known about it in 2005 and yet nobody hears anything about that until 2013.

MS. PARKER: There was testimony at trial that a couple of people there knew that they were using the information. Okay? That is in the record. I'm not disputing that.

What I am saying, though, they didn't know the whole story. They didn't know the whole story and once they

found out, once the infringing products were about to hit the market we filed the lawsuit. And because of those circumstances, I just respectfully submit I don't think that that is information that would be appropriate for Your Honor, respectfully, to use in analyzing the enhancement.

THE COURT: We're near the end of your time. Just one other question. It was technically I think raised by their motion. It relates to willfulness, so maybe you will know the answer to it. It has to do with waiver and really whether I should be evaluating if there was sufficient evidence of willfulness.

I think this doesn't get argued but gets mentioned towards, in a footnote maybe in their brief, and you all argue at least footnote arguments or things that are just listed and efforts to revive them from a 50(a) motion are waived.

Is that something you could address?

MS. PARKER: I'm not sure what the argument is in the footnote. What is the ...

THE COURT: Basically, it is they are trying to reserve their right to have me decide, for instance, whether there is substantial evidence of willfulness. Your position I think is they have waived their chance to do that.

MS. PARKER: Yes, Your Honor. And besides that, we think it would be inappropriate under *Read* and the other

cases that have interpreted *Read*.

Your Honor, may I add one more thing? I know my time is about up.

THE COURT: Sure.

MS. PARKER: If I could add one more thing.

It is totally up to Your Honor's discretion in terms of whether or not to enhance, and the amount is totally up to Your Honor's discretion as well.

But if you step back and just think about what happened here, regardless of when somebody found out or put all that aside, this is a situation where an individual is in a position of trust with a corporation. There is just no question about that. He was in a position of trust and he abused that. He abused it by taking information that he shouldn't have shared. He shared it. He knew what he did was wrong. That is what led to the cover up.

That is not behavior that is appropriate for our corporations. It is the exact type of behavior that should be punished. And I respectfully submit Your Honor should send a message of deterrence for Gilead and for other corporations as well. And because of that -- and again, it was totally in Your Honor's discretion. And because of that, we didn't even put this in our brief, because, again, it is up to you.

But given all these factors, in case it would be

helpful to the Court to hear our position on this, looking at all the cases out there, all the cases that have decided that have awarded enhanced damages, this fits within the cases where it is appropriate to at least double. And this is really bad corporate behavior here. This is something that we should send a message, it should not be allowed. You shouldn't let this happen. We don't want it to happen again. They knew what they were doing. They knew what they were doing and they covered it up.

So thank you, Your Honor, for your time. And if you have any other questions, I'm happy to answer them. Otherwise, I'll sit down.

THE COURT: Not at this point. You are out of time, but I will give you a couple of times for rebuttal, if you want.

MS. PARKER: Thank you, Your Honor.

MR. McCANN: May I approach, Your Honor?

THE COURT: You may.

(Slides passed forward.)

MR. McCANN: Good afternoon, Your Honor. I think I'm the last batter today.

THE COURT: Good afternoon.

MR. McCANN: Doug McCann from Fish & Richardson. I'm going to address the issue of enhancement.

Just very briefly on the law, Your Honor. This

goes toward some of the questions you were asking about willfulness. I think you understand that there is a willfulness finding here but as the Supreme Court and other courts have told us, willfulness, a finding of willfulness is the entrée into whether the Court will enhance or not. It does not require enhancement. That is within the Court's discretion.

As the Federal Circuit said in the remand on *Halo*, willfulness, the finding of willfulness is a factor for you to consider. It is not the factor for you to consider.

Your Honor also understands, the cases tell us, that this is about punishment. This is about deterrence. And I was interested to see that counsel sort of ended with a request for doubling, and that's the first we had heard as to what they thought the appropriate punishment here was, and I think that's kind of telling.

You know, this was obviously a very significant patent case. You know and you've heard the statements of the attorneys that it's the largest verdict I guess in U.S. history. And I thought it surprising that when the Court is going to punish, the Court is acting at the height of its power when it's going to punish somebody. And I certainly have been as a lawyer in court many times where some party was about to be punished and I never had a situation where you didn't go into it explaining what the appropriate

punishment was with detailed reasons as to why that was appropriate in this particular case, and I don't think you have really gotten much guidance from counsel on that point alone.

I also think, and this is related to some of the questions that the Court was asking counsel, if you are going to deter and punish, does that make sense here, and who are you punishing? So what I have is a timeline from 2000 to 2013. Your Honor is familiar with a lot of facts, but I've put in a red box. I have on the left side outside the red box Dr. Schinazi and Dr. Watanabe, and then I have in the red box Mr. Clark and Dr. Sofia and Dr. McHutchison.

And I think one of the questions the Court should be asking itself when trying to determine whether it should impose any kind of punishment here, is the path of sofosbuvir something that should be deterred? If you think of the evidence in the case, Dr. Otto was the chief scientific officer of the company, and he tells the chemists, I want you to go and look for ideas.

And when I'm making my presentation, Your Honor, I don't intend to say things contrary to our JMOL argument. It's really sort of, even crediting a lot of the arguments that Idenix has made, Dr. Otto said, go look for ideas, go find the holes, things that other people are not doing.

Jeremy Clark was walking into his office with a Novirio patent. The testimony was, he said, I thought of making a methyl up and fluoro down with all of the four natural bases, and I looked and I don't see that anybody else is doing that. And he specifically has, I believe he testified, and he said Merck patent application and Idenix patent application. He said look here. I don't see that here.

And so the question, Your Honor, as you try to decide am I going to impose punishment here, do you want Dr. Otto to say to Mr. Clark or Dr. Otto of the future, well, although I don't see -- you know, I see the halogens, but I don't see fluorine anywhere in the specification. It's possible that a couple years from now, Idenix will get new claims. It's possible about six years after that, a patent. It's possible another nine years after that, a District Court reviewing the record might conclude there wasn't a clear and unmistakable disavowal of fluorine. So it's possible that some day we'd be subject to treble damages, so actually, you'd better go do something else. That is not something that should be deterred.

If you consider the issue of enhancement to be this issue of piracy, there are no pirates in that red box. In fact, if they are anything, they are heroes. Dr. Sofia, in fact, received an award, Hero of Chemistry, because of

that wonderful thing he did in taking the start that Clark had and turning it into what became sofosbuvir.

THE COURT: All right. So, of course, from other punishment contexts you've dealt with, you're familiar with the fruit of the poisonous tree doctrine. Why shouldn't I apply something like that?

Assume for the moment that Dr. Schinazi did all the bad things that he was alleged to have done. Why shouldn't I punish and send a message that all the heroes afterwards, good for them, but too late for at least Gilead?

MR. McCANN: Well, let's consider Dr. Schinazi to be the pirate in our scenario here. You're not punishing him and you're not punishing the Schinazi of the future. The facts of this case are Dr. Schinazi did what he did. He was a founder of Pharmasset and he owned a lot of Pharmasset stock, and Gilead paid the $11 billion for Pharmasset and he made a lot of money. I think there's some evidence it is something like $400 million.

No one is going to be, this Court is not going to be, if it sanctions Gilead or enhances Gilead, he's not giving any money back. There's no disincentive to the next Schinazi. All the Court would be doing would is punishing Gilead, taking money away from Gilead that could be used for the next great improvement or the next effort anyway to

improve drugs.

So I actually don't think a deterrent here would actually have an effect on Schinazi because he's out of the picture. He actually -- it's not in the trial record, Your Honor, but it is in the record before the Court. He was forced out of the company in 2005 because Pharmasset had concerns about him. And Dr. Sofia, you know, said, I wouldn't even have joined Pharmasset if he was there.

I guess my point on that is, Pharmasset took corrective action already, and any punishment here only punishes the good work that Pharmasset did and not whatever Dr. Schinazi did in the days when he was involved.

THE COURT: Well, I think part of the whole theory of this is, as you said yourself even, the Dr. Ottos of the future, what would we want him to do? If one were to apply something like a fruit of the poisonous tree doctrine, why wouldn't that put Gilead on notice that if you are going to spend $11 billion? Let's say you'd better be super diligent and make sure that what you are buying isn't itself somehow the fruit of the poisonous tree or be prepared to pay double or triple damages.

MR. McCANN: If I was advising Gilead of the future, I would say this drug is a public good and you need to bring it to the market whatever what the risks are on that. I don't know of any -- you know, I just don't see

what is the connection to what Dr. Schinazi did and how does that lead to the development of sofosbuvir itself? And let me explain what I mean by that, Your Honor. It's not a theft of trade secrets case. It's not.

Dr. Schinazi, according to Idenix, Dr. Schinazi learns that Idenix thinks that 2' methyl up is significant and has activity. That's the gist of what he supposedly tells Dr. Watanabe and that's in 2000 and 2001. It's not the case that Idenix kept that close to the vest for all time. They published it in a patent application. So everything that Schinazi supposedly learned and gave to Pharmasset by November of 2001, that's out there for all of the public to learn from. And again that is exactly why we have patent applications that are published, because we want the public to learn from that.

The Supreme Court in *Halo* said something along the lines of, you want, when you are trying to determine whether to enhance or not, you want a balance on the one hand protecting the interests of the patentee, but on the other hand, not discouraging, and the words they used were, imitation, or imitation through refinement that is, in fact, often the heart of the next invention. That's what the Supreme Court said. Again, that's what we have here.

If you have Jeremy Clark look at their patent application and say, I see methyl up, fine. I don't see a

methyl up and a fluoro down. Let's try that. You want that to happen, Your Honor. You don't want to discourage it. Even if it ultimately proves down the road that they're wrong and they're going to infringe a patent claim and they have to pay compensation, you still want that R&D, that effort to go forward.

Now, just very briefly on Dr. Schinazi, a little bit more on him. It was just this allegation that the 2' methyl up is the bedrock of Sovaldi and Harvoni. You already heard some of this, Your Honor, in the earlier presentations.

Again, when you are looking at whether to exercise your discretion to enhance, what is the importance of this 2' methyl up information that's published in Idenix's patent application and is out there for the world to benefit from?

You heard Mr. Griffith talk about the 12 companies that were pursuing compounds, all that had the 2' methyl up. I guess under the Idenix view of the world, they're all pirates. We have a whole fleet here. Only one of those compounds succeed, sofosbuvir, the others all failed, notwithstanding the fact that they had the 2' methyl up. And I think that is also important in considering whether to exercise your discretion to punish.

The idea of the 2' methyl up is not the entrée

into the cure for hepatitis C. It's the work that Michael Sofia did and Jeremy Clark before him, and why would you want to punish that?

Now, I do want to go to the *Read* factors briefly, Your Honor, and I want to emphasize at most number five, the closeness of the case.

First, when we're talking about the closeness of the case, it is still true. We used to have that objective test under Seagate, it's now gone, but the Federal Circuit has made clear that even after *Halo*, you can still look at the objective reasonableness of the accused infringer's positions in determining whether to exercise your discretion, and that's *WesternGeo*.

I want to point to really, I guess, two areas on the closeness of the case. The first is the claim construction and the second are the 112 arguments.

If Your Honor thinks about why was the claim construction a close question and why are the 112 issues close questions, it really has to do with that patent specification and the fact that there's no F there. You really go back into the room with Clark and Otto, looking at that and, you know, do you see possession of the invention? Do you see them teaching how to make this?

Those are the reasons why the 112 arguments, however you ultimately come out, I think at least it's

certainly our position that these are very close calls. And the same thing with the claim construction. I was looking at the Court's claim construction opinion, and you specifically mentioned that the failure to disclose fluorine at the 2' down position gives the Court pause. It could have been the case, Your Honor, that you could have stopped at that pause and said, you know what, there's no fluorine here. I'm not going to construe the claim to cover fluorine. There would be no infringement. There would be no willful infringement. We would not be talking about enhancement. It was a complete defense.

The same could also be true with enablement. You might determine ultimately that the patent is not enabled, the full scope of the claim. And, again, then there's no valid claim and no infringement, no willful infringement and no enhancement. And so I think that that is something that the Court should consider I think as one of the most important issues in determining whether to enhance here or not.

I've talked a bunch about Watanabe, Your Honor. And I did want to just sort of touch briefly on -- this is the point I failed to mention earlier. I wanted to make the point. You heard a lot about Dr. Schinazi and what he did, and Your Honor sees there's sort of a gap in the story. Schinazi tells Watanabe, hey, they're looking at 2' methyl

up at Idenix, and then around this time Dr. Hassan is making 2' methyl up. And there's an actual fight within the company, within Pharmasset, where did Hassan get the idea? And Schinazi says, well, I told Watanabe. He must have told Hassan. And Dr. Otto is saying, well, I thought Hassan, you know, came here from his last employer knowing this information. That's actually what Dr. Hassan had to say. So this sort of fight, but even Idenix doesn't say that Clark had anything to do with that. He's sort of separated in time by a year from whatever Dr. Schinazi is doing to what his effort is with the methyl fluoro compound. I mean, there's a big disconnect between the bulk of the evidence that they say is the piracy and the effort that led ultimately to 6130.

Your Honor knows it's not improper to look at a published patent application. In fact, that's often what happens in research and development. We know from this very case that certainly Pharmasset was looking at what Idenix was doing, but Idenix was looking at what Pharmasset was doing. And so here on slide 3019, we have an internal Idenix communication where JP, that's John Pierre Sommadossi, is still keen that we try to make a 2', fluoro 2' methyl analogue because he heard from Schinazi that was good. There's nothing necessarily improper looking at your competitor's work.

On this issue of copy, again, I've already touched on this, so I will be very brief, Your Honor. But I did want to pick up a little bit on what Mr. Singer was talking about, about how counsel had said that, you know, a person of skill in the art would not make a prodrug with an inactive compound. He said that's exactly what Dr. Michael Sofia did.

This slide was presented at trial. This is how Dr. Sofia described how you arrive at sofosbuvir. He was studying 6130, and he noticed there was an inactive metabolite that was being generated, this 6206, which has a methyl up and fluoro down. It has a different base. It was inactive and there was a lot of it being thrown off. He was trying to figure out why that was. And he figured that, he learned through his work that if he made the triphosphate of that, it was really active. But he had a lot of trouble, or he had a big task in figuring out, how do I actually get that into your body, and that's what led him to do that prodrug work. Again, very far removed from anything Dr. Schinazi did and certainly not something that the Court should be discouraging or punishing.

So this is the *Halo* quote I was referring to before, Your Honor, just for record. It's at page 1932 of the opinion. Imitation and refinement imitation, these are the things necessary to the invention itself and the very

lifeblood of a competitive economy. It's not wrong to say I think that they're not doing this. I will go ahead and some day be proved to be incorrect because of a claim construction ruling that goes against you. That's not something that is an act of piracy.

Most of the rest of this, Your Honor, we've already talked about. I think maybe the last thing I will focus on is concealment. Your Honor touched on it before. I think Pharmasset was very open about what it was doing. It was publishing its work as many small companies do, and I think Idenix was very well aware, record shows, of what was happening. They did not complain at the time. And I think Your Honor has in the record in front of you the D.I. 556, where Lorie Ann Morgan from Gilead makes the point in her declaration that not only was Pharmasset not concealing at the time it was doing its work, but later on when Gilead acquired sofosbuvir and it got into sort of this worldwide dispute with Idenix, that was all about that '600 patent, which is their methyl fluoro patent, and its overseas counterparts.

At no time did Idenix ever say in any of the settlement discussions they had during the couple years of litigation, you need to take a license to this '597 patent. The first we knew of it, it was a bolt from the blue, is when they sued us in this case, which really began in

Boston. So not only no concealment, but not even an allegation until the case began. That was the first notice that Idenix actually considered Gilead to be infringing the '597 patent.

So that's all I have, Your Honor, unless you have any specific questions.

THE COURT: Yes, I do. First, what about this point about any credibility assessments that I may have made sitting here through the trial? Is it fair for me to factor that in or not?

MR. McCANN: It is, Your Honor. It is within your discretion to make, to weigh the evidence and to make determinations, including credibility, in assessing whether you should or should not enhance.

So I do think that, although we have a JMOL on willfulness and we have our arguments about whether there's substantial evidence for that, but if you decide, yes, there was and there is a willfulness finding, yes, then that is a factor you should consider, that there is willfulness, but then you, yourself, in exercising discretion can look at the evidence, weigh the evidence, and ask yourself, do I think, some of the cases talk about did the defendant have evidence of its own invention separate from learning it from the other side. In other words, do you credit Dr. Hassan and Raji Kahn as they had the methyl up idea separate from

whenever Schinazi learned from Idenix. You can weigh that evidence and decide based on that evidence in part, I'm not going to enhance. You can look at the, what Clark and Otto's discussion was and say, yes, it was legitimate, or I credit that testimony where Dr. Otto says -- I mean, he can't be making this up. There is no F in that specification. There's no F there. Go ahead and make it. You can credit that separate and apart from the fact that you've determined that there should be a willfulness verdict upheld.

THE COURT: There seems to be a tension there, because if I uphold the willfulness verdict at least based on a finding of substantial evidence, then you have to infer that the jury made certain credibility determinations that led it to that conclusion, it would seem, and that was completely, and I don't think you are arguing to the contrary, but that was their province to do. It is not my job to make a credibility determination. So it would seem odd that I could question that for purposes of enhancement, but your position is that I can.

MR. McCANN: I guess first, just for the record, Your Honor, we did preserve the argument that willfulness ultimately is something, it should be something for the Court and not the jury. I understand that the Federal Circuit still has its cases that say it's still a jury

issue. That is something that is winding its way through the courts. So it was, in this trial, it was given to the jury to make that decision.

I don't think there is anything at all though inconsistent with you analyzing the same evidence and asking yourself whether or not you should enhance in making determinations as to what would credit or not credit in doing that. I mean they found willfulness but there is no special interrogatory, so I guess nobody exactly knows why they found willfulness. And it could be that they found certain testimony credible and others incredible. We don't really know that.

We're not in a JMOL context when we're talking about enhancement where you must consider all the evidence and weigh it in a light most favorable to Idenix in determining whether to uphold willfulness or not. We're talking about whether you should use your discretion in how you view the evidence you heard in determining whether there was piracy here by Gilead.

THE COURT: You mentioned you do say that there is not substantial evidence for willfulness, but if I'm not mistaken, it's in a footnote or you have various arguments you are trying to incorporate by reference to briefs that would well exceed the page limits that we set on the JMOL motions.

Is it really Gilead's contention that all those issues are ripe for me to decide and they didn't waive them?

MR. McCANN: I'm happy to say, Your Honor, that Mr. Scherkenbach told me that he would address that if Your Honor posed that question.

THE COURT: All right.

MR. McCANN: Before I turn it over to him, do you have any other questions?

THE COURT: I do.

MR. McCANN: Do you want to cover those first, Your Honor?

THE COURT: I think they even use this phrase in their briefing, but the sort of heads I win/tails you lose scenario. They point out, and incorrectly, that while it is a large number that has already been awarded against your client, it is all, strictly speaking, compensatory. And if you don't enhance, in this case or let's say more generally a case where there is willfulness, then what is to stop an accused infringer from saying, look, worst case scenario, I lose this case and I just pay what I fairly owe. I don't have to worry about anything beyond that.

MR. McCANN: First, Your Honor, I don't think that one must follow from the other. Plenty of courts have willfulness findings from their juries and don't enhance. And so presumably they think, under those circumstances, no

further punishment was required. And that is what I'm saying is the case here.

This is a very substantial verdict, and that does have I think a deterrent effect on a company who is pursuing a drug. I think it acts as a very negative effect on companies who might be pursuing an acquisition, what are we buying here? Because even as a company that is as large and successful as Gilead, $2.54 billion is devastating. It is a huge verdict that will have, and does have, a great impact on that company.

I don't think that, you know, counsel asked for double that. Under these facts, to me, that makes absolutely no sense. If the issue is you had an employee or not even an employee but a person associated with your company who did some things he should not have done but all of that in a way was mooted by the fact that Idenix published that very same information, you have other persons associated with your company that you someday are going to acquire, you look at it and think, well, this is probably going to be clear and go ahead and then prove to be wrong. The $2.54 billion Gilead has to pay here would give I think a lot of companies pause: Do we want to take this on? This is huge.

I don't think that it is necessary to add money to a judgment, if that is the only way you can have

deterrence. The mere size of the verdict is a huge impact on this industry, and that is enough, if we even get to the point of thinking some deterrence is required, which, again, Your Honor, I believe under the facts of this case are not supported.

THE COURT: And you mentioned Schinazi was forced out of the company in 2005 but noted I think that is not in the trial record.

MR. McCANN: It is not.

THE COURT: Is it your view I could consider things that are not in the trial record for this enhancement decision?

MR. McCANN: It is my view, and also it is Idenix's view, as they made clear in their opening brief.

THE COURT: All right. If Mr. Scherkenbach wants to address the waiver et cetera question, we'll hear that before we turn back to Ms. Parker.

MR. SCHERKENBACH: Thank you, Your Honor. Just briefly on that.

I think it is useful to go back and look at what actually happened on the JMOL on willfulness. I'll just focus on willfulness because that was your question.

So during trial, Gilead made oral motions for judgment as a matter of law that included willfulness. Then in the next day or so, we filed a Rule 50(a) written motion

for judgment as a matter of law that included willfulness.

And the Court then, subsequently on the record at trial, reserved judgment on JMOLs actually on both sides. So the Court never actually addressed the JMOLs on the willfulness, and some other issues too but let me stay focused on willfulness.

And so when it came time to do our post-trial JMOL motion, what we thought we did and what we intended to do was to say essentially on those other issues, we renew the JMOLs that had been made at trial because as to those, the Court had not definitively ruled one way or the other.

On this page limit issue, there isn't, certainly there was no attempt to end run on that. If you go back and look at each side's Rule 50(a) motions as filed during trial, each side addressed willfulness and some of these other issues, the Merck issue and the priority issue, in writing in roughly the same number of pages, so it's not like Gilead got a bunch of pages and Idenix never had a challenge to response. The record is really the same on both side for those issues.

THE COURT: Well, I can at least say, subjectively, I did not understand that when you all said you were going to raise issues in post-trial motions, and I think you came up with a 25 page limit, but I don't recall exactly.

MR. SCHERKENBACH: We did.

THE COURT: I didn't understand that I was then going to be asked to revisit issues that had been briefed during trial and which I had reserved judgment. I certainly would have given you more pages if I thought that was what was going to happen.

MR. SCHERKENBACH: Well, and --

THE COURT: Let's, just for the moment, if that was my subjective experience, why should I not say too late for these issues?

MR. SCHERKENBACH: Well, I think our real concern is with any sort of a finding -- and it is a little hard to tell what Idenix is arguing here because they used the word "waiver," sort of the magic word, and we certainly don't want to have any finding or suggestion that that these issues were waived for purposes of appeal. That really is the primary driver for Gilead having renewed these motions.

I think if we can get past that or get some comfort on that? You know, we're not expecting the Court to revisit in detail the Merck issue or the priority issue and, frankly, even the willfulness issue. That isn't fundamentally what is driving us. It is really some sort of waiver suggestion or suggestion that would say not only, Judge Stark, should you not, do you not have to reconsider it, but it is lost for appeal as well. Because we think we

clearly preserved it for appeal.

THE COURT: Okay.

MR. SCHERKENBACH: Thank you.

THE COURT: Thank you very much.

Ms. Parker, come back and address whatever you would like.

MS. PARKER: Thank you. Your Honor, I think four points cover.

First of all, I think I know the answer to Your Honor's question. And I think I know why there are no cases out there on enhancement that talk about the Court considering credibility of witnesses and reexamining the willfulness finding. It's because of the Seventh Amendment. And so I believe that the Court cannot reexamine facts that are found by the jury either found expressly or implicitly. So I believe that is the answer to Your Honor's question.

Next point. Counsel asked, well, who are you punishing, and tried to say it is not Gilead, tried to distance themselves.

If we can pull up slide 25. 25, please.

There is a lot of evidence in the record as to what Gilead did, not just Pharmasset. So when it purchased it, it has access to all of these documents. They knew about Dr. Schinazi. These same key Pharmasset employees went over to Gilead, and Gilead continued to work on the

product. So it's not just Pharmasset. They can't divorce themselves from it.

They also talked a lot about the compensatory damages verdict was something that was important, affected the company. And I just want to point out -- if we can pull up slide 45. For the record, the record evidence is that Gilead has $32.4 billion in cash and cash equivalents, and that from its misconduct here.

Let's go to slide 45.

That is the *Arctic Cat* case where the Court said enhancement is "particularly warranted" where the defendant "is a multibillion dollar enterprise and the market leader -- due in significant part to sales of products found to willfully infringe."

The next point I want cover is argument from counsel on closeness of the case. Your Honor knows that is only one factor, so even if the Court were to believe that there was some issue that was close, I just bring to Your Honor's attention the *Dominion* case that was from the Eastern District of Pennsylvania last year. That is a case where the Court found enhancement in doubling but also found that there was the closeness of the case factor went against the plaintiff but nevertheless that other factors were strong.

And then, finally, counsel said, well, what

message are you sending? What message would you be sending?

Well, Congress says because of enhancement, because of the statutory structure that is set up, Your Honor need to consider the message to the inventors, to Dr. Sommadossi and Dr. LaColla. They're the ones that came up with this idea to begin with, and they're the ones who are protected. They are the ones that are covered by this enhancement provision. They're the ones that started off as the heroes here. So we shouldn't forget them and their role.

Unless Your Honor has any questions?

THE COURT: The only other one, it was mentioned, as you heard, Dr. Schinazi was sort of taken care of in the defendants' view in 2005 when he was evidently pushed out of Pharmasset.

Do you disagree with that? And more so, do you disagree that I can consider things like that or am I limited to only what was the jury verdict?

MS. PARKER: You are the not limited to what was the jury verdict. You are limited to what is in the record. And frankly I don't know. This is the first I have heard of this. I don't know whether it is in the record or not. If counsel says it is, I'm sure it probably is, but I just, I can't speak to that.

But I think the point is there is all that happened separate from him. It's not just him. Gilead

bought that company knowing what they were buying. They knew they were buying Dr. Schinazi. They knew that they were buying the company. They knew about all the -- they acquired all those documents. They inherited all that. They knew about all that. And then, remember, Dr. Schinazi was still being paid by Gilead at trial here. Remember the testimony on his videotape deposition that was shown to the jury is that he was being paid $800 an hour for the trial, for his work at the trial. So it's not that he was gone and done for forever back then.

Thank you, Your Honor.

THE COURT: Thank you.

Mr. McCann, anything further?

MR. McCANN: Just briefly, Your Honor. A couple of things.

Counsel said that Gilead has made something like $32.4 billion and that it is all from wrongful conduct.

Really, that is unsupportable. That drug has succeeded in a way it has or exists because of Sofia, not because of Ray Schinazi.

Your Honor asked some questions about whether you can weigh the evidence. You asked a couple of times at least while I was sitting here.

I think in the briefing, if you look at the case *Enplas Display Device v Seoul Semiconductor* or the case

***Sprintcom v Time Warner*, those are at least two examples where the Court determined enhancement is going sort of back to the record and assessing it separate and apart from what the jury had to say.**

I think that is really it, Your Honor, unless you have any further questions.

THE COURT: No, I don't have anything further.

Ms. Parker.

MS. PARKER: No. Thank you, Your Honor.

THE COURT: All right. Well, our time is up. The arguments have been very helpful on all issues. I appreciate it very much. We will take the motions under advisement; and we will be in recess.

(Oral argument hearing ends at 4:00 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Brian P. Gaffigan
Official Court Reporter
U.S. District Court